HEMOCHRON *Signature Elite*®

Whole Blood Microcoagulation System

Operator's Manual
English

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This manual is published by International Technidyne Corporation (ITC) for use with the HEMOCHRON *Signature Elite* Whole Blood Microcoagulation System.

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INTENDED USE

The HEMOCHRON *Signature Elite*® Whole Blood Microcoagulation System is a battery-operated, hand-held instrument that performs individual point-of-care coagulation tests on fresh or citrated whole blood. These tests include: Activated Clotting Time (ACT+ and ACT-LR), Activated Partial Thromboplastin Time (APTT and APTT Citrate), and Prothrombin Time (PT and PT Citrate). The system is intended to be used only with test cuvettes that are available from ITC.

Data management capabilities are included with the instrument. These capabilities include storage of up to 600 patient results and 600 quality control results, designation of quality control levels, tagging of test results with date and time, entry of Patient ID and/or Operator ID or Operator PIN, and printing of results.

HEMOCHRON® *Configuration Manager* software is included. This software allows the user to connect a personal computer to the instrument and perform system configuration functions using the fast and convenient Microsoft® Windows® user interface. HEMOCHRON *ReportMaker*™ software, provided separately, allows the user to connect a personal computer to an instrument and perform various data management and data reporting functions.

For *in vitro* Diagnostic Use.

SUMMARY AND EXPLANATION

Events that lead to formation of a blood clot are simplified in coagulation theory into two interactive coagulation cascades that are referred to as the **intrinsic** and the **extrinsic** pathways.

The clotting factors involved in these pathways are numbered I through V and VII through XIII. The intrinsic pathway begins with the contact activation of factor XII and, through the interaction of several coagulation factors, results in the conversion of soluble fibrinogen to insoluble fibrin strands. The extrinsic pathway is initiated through the interaction of tissue factor with factor VII. Platelets, essential co-factors in this reaction, provide the platelet phospholipid surface on which coagulation reactions occur.

Activated Clotting Time (ACT+ and ACT-LR), Activated Partial Thromboplastin Time (APTT and APTT Citrate), and Prothrombin Time (PT and PT Citrate) tests are general coagulation screening tests that are used to measure the functionality of the blood coagulation cascade. The ACT test is the method of choice for monitoring heparin therapy during cardiac surgery and **PCI**. Fresh whole blood is added to an activator (Celite®, silica, kaolin, or glass particles), and then timed for the formation of a clot. The type of activator used will affect the degree of prolongation of the ACT to a given heparin dose.

The HEMOCHRON® Jr. ACT+ test uses a mixture of silica, kaolin, and phospholipids as an activator to create a rapid and highly sensitive alternative to existing ACT tests. This test demonstrates linearity at heparin concentrations ranging from 1.0 to 6.0 units of heparin per mL of blood, and it is not affected by high dose aprotinin therapy.

The HEMOCHRON Jr. ACT-LR test uses a Celite activator due to its excellent heparin sensitivity. The test demonstrates linearity at heparin concentrations up to 2.5 units of heparin per mL of blood. The test is not intended for use with aprotinin therapy.

The HEMOCHRON Jr. APTT test measures the intrinsic coagulation pathway and involves all coagulation factors except factors VII and III (tissue factor). The APTT test improves the PTT test through use of a contact activating substance, which standardizes activation of Factor XII to provide a more precise and sensitive assay for low level heparin monitoring. The HEMOCHRON Jr. APTT test is formulated to provide optimal heparin sensitivity at heparin concentrations up to 1.5 units of heparin per mL of blood.

The HEMOCHRON Jr. APTT Citrate test performs the same measurement as the APTT test, using a citrated whole blood sample.

The HEMOCHRON Jr. PT test measures the extrinsic coagulation pathway and is sensitive to coagulation factors VII, X, V, II, and fibrinogen. PT results may be abnormal in patients with liver disease or Vitamin K deficiency. The test is widely used to monitor oral anticoagulant therapy. The PT test is a unitized test system utilizing a highly sensitive thromboplastin for improved specificity and sensitivity.

The HEMOCHRON Jr. PT Citrate test performs the same measurement as the PT test, using a citrated whole blood sample.

> ***Note:*** *HEMOCHRON Configuration Manager V3.0 or higher is required and is included with the HEMOCHRON Signature Elite instrument.*

PRINCIPLES OF OPERATION

The HEMOCHRON *Signature Elite* Whole Blood Microcoagulation System provides many features for ease of use and reliability, including a patented clot detection system, a data storage module, interfaces for a laboratory computer and/or printer, a streamlined user-interface panel, and an integrated barcode scanner.

The system measures whole blood clotting times using HEMOCHRON Jr. disposable single-use cuvettes. Each cuvette contains all of the reagents necessary for a specified test.

The operator inserts a cuvette for the test into the instrument and then (if desired) enters information about the sample or scans the information from a barcode using the integral barcode scanner. After the cuvette has warmed to 37 °C ±1.0 °C, the instrument beeps, signaling the operator that a blood sample can be added to the cuvette and the test started.

The operator then places a drop of blood in the sample well of the cuvette and presses the **START** key. The instrument measures the required volume of blood and automatically moves it into the cuvette test channel, where it is mixed with reagents. The remainder of the blood sample, not needed for testing, is automatically drawn out of the sample well and into an enclosed waste channel on the cuvette.

After mixing with the reagent, the sample is moved back and forth at a predetermined rate within the test channel and monitored for clot formation. The test channel is maintained at 37 °C ±1.0 °C during the test.

The rate of movement of the sample is monitored by a series of LED optical detectors that are aligned with the test channel. When the blood clots, the flow of the blood sample within the test channel is impeded, reducing its rate of flow between the optical detectors.

This reduction in flow below a predetermined value signals to the instrument that a clot has formed. The instrument also emits an audible beep when clot formation occurs, indicating the end of the test. An internal timer measures the elapsed time between the start of the test and the clot formation. During the test, the whole blood clotting time (in seconds) is displayed.

APTT and APTT Citrate results are displayed as plasma equivalent (PE) values, PT and PT Citrate results are displayed as the International Normalized Ratios (INR) and PE values, and ACT+ and ACT-LR results are displayed as Celite ACT equivalent time.

The results will remain on the display while the cuvette remains in the instrument.

The result can be automatically printed along with the time and date the test was run, the Patient ID, Operator ID, and other information, if entered. The result is also saved in an internal database. Up to 600 patient test results and 600 quality control test results can be stored in the instrument for later printing or downloading.

Individual HEMOCHRON *Signature Elite* instruments can be customized so that designated quality control tests must be performed whenever a specified period of time has elapsed and so that information for cuvettes and liquid controls can be included in test records. The instruments can also be configured so that only authorized operators can operate the system and/or operators cannot perform certain functions such as deleting test results from the instrument database. These and other configuration options are entered using HEMOCHRON *Configuration Manager* Software on a personal computer.

Definitions and Terms

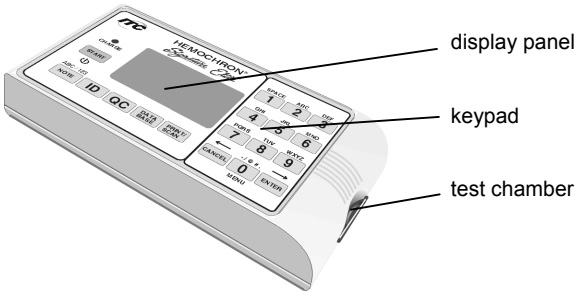
The following acronyms and abbreviations are used in this manual, instrument screens, and printouts:

ACT	Activated Clotting Time
APTT	Activated Partial Thromboplastin Time
CVlot	Cuvette Lot Number
DB	Database
EQC	Electronic Quality Control (System Verification)
HCM	HEMOCHRON Configuration Manager
INR	International Normalized Ratio
idms	Integrated Data Management System
LQC	Liquid Quality Control
OID	Operator Identification Number
PID	Patient Identification Number
PIN	Operator Personal Identification Number
POCC	Point of Care Coordinator
PT	Prothrombin Time
QC	Quality Control
QClot	Quality Control Lot Number
TQC	Temperature Quality Control

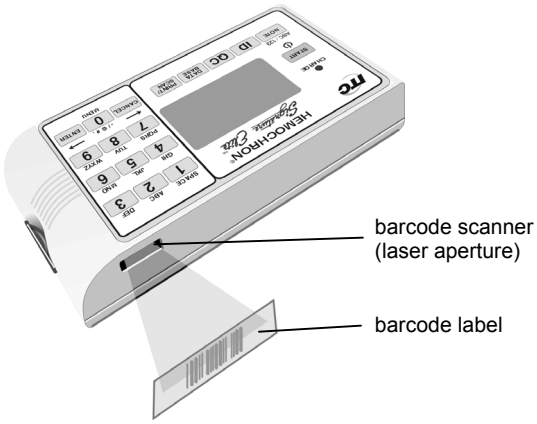
DESCRIPTION

The HEMOCHRON *Signature Elite* instrument is a hand-held device. It contains a **test chamber** which warms a test cuvette to the required temperature, and it performs all operations to measure the clotting time of a whole blood sample after it is placed in the test cuvette and the test is started by the operator.

Operator instructions are shown on the **display panel**, and the operator enters commands and information using the **keypad**. When the test is completed, the results are shown on the display panel and stored in system memory for printing or downloading.



The instrument includes a **barcode scanner** for reading of barcode labels.

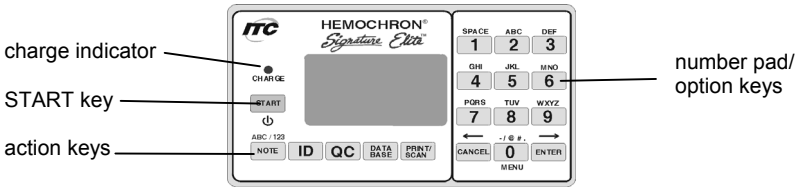


Keypad

The front panel contains a keypad with various action keys as well as a number pad. The operator uses the keypad to select a command or enter information.

Action keys display a menu of commands according to the label on the key. For example, the **PRINT/SCAN** key displays printing commands and enables scanning. **Number pad** (or **option**) keys are used to enter characters for IDs or numbers for selection of commands.

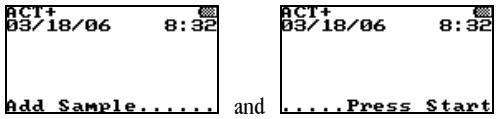
Note: *The **0** (zero) key is used as both a numeral key and an action key.*



Key	Purpose
START	Turn on the instrument or turn off instrument. Initiate a test after the test cuvette has reached 37 °C ±1.0 °C and the sample is added.
PRINT/SCAN	Print results on an external printer for the last test result, patient database, quality control database, or all test results for a specified patient. Test the printer. Enter a customized header. Print instrument system information. Scan a barcode ID when **Enter PID**, **Enter OID**, **Enter PIN**, **Enter CVLot**, **Enter QCLot**, or **Scan Lot** is displayed.
NOTE	Select a laboratory-defined note (from nine choices programmed via HEMOCHRON *Configuration Manager*) for entry into the record for the current test. Toggle between alphabetic (**ABC**) and numeric (**123**) characters when **Enter PID**, **Enter OID**, **Enter PIN**, **Enter CVLot**, or **Enter QCLot** is displayed.
ID	Enter a Patient ID or Operator ID.
QC	Specify that the test being run is a normal (level 1) control or an abnormal (level 2) control. (For QC Lockouts) Display the length of time remaining before Quality Control testing for a particular test must be successfully completed. Initiate an EQC (Electronic Quality Control) test.
DATABASE	Display the number of patient or QC test results that are currently stored in the instrument and the number of additional test results that can be stored. Display results of the stored patient or QC tests. Delete patient or QC records. Initiate POCT-1A communication.
0 through **9**	Select a menu option. Enter information (e.g., a Patient ID, an Operator ID, cuvette lot number, QC lot number, a time, or a date). Display the main menu by pressing the Zero key when no tests are running and no menu is active.
CANCEL	Cancel an operation and return to the previous state.
ENTER	Accept an entry (e.g., a Patient ID, an Operator ID, a time, or a date).

Display Panel

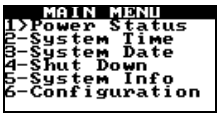
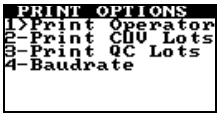
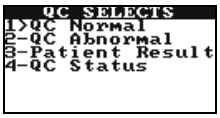
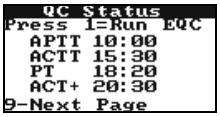
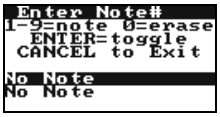
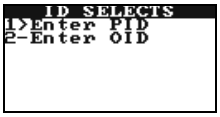
The instrument communicates with the operator by means of the display panel. For example, **Add Sample** and **Press Start** are alternately displayed after a test cuvette reaches temperature:

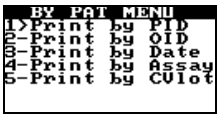
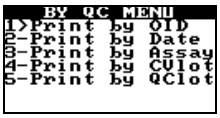
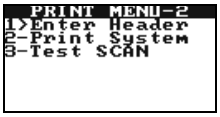
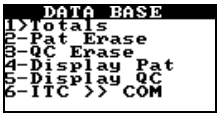


The display is illuminated to enhance visibility in low light conditions. To conserve power during battery operation, the display is not illuminated when the test well is empty or when a test is running. The display is momentarily illuminated after a key is pressed or when results of a completed test are displayed. While a test is running, the display can be momentarily illuminated by pressing the **CANCEL** key, the **ENTER** key, or any numeric key.

Menus

The action keys are used to display and activate various commands for operating and configuring the system. The principal menus are shown below:

Menu	Commands	Access
Main Menu		Press the **0** (zero) key when no tests are running and no other menu is active.
Configuration Menu		Press the **6** key while the Main Menu is displayed.
Supervisor Menu		Press the **5** key while the Configuration Menu is displayed, enter the supervisor PIN at the prompt, then press and hold the **Enter** key.
Print Options Menu		Press the **6** key while the Supervisor Menu is displayed.
Communications Menu		Press the **7** key while the Supervisor Menu is displayed.
QC Selects Menu		Press the **QC** key while a cuvette is inserted in the instrument.
QC Status Menu		Press the **QC** key before a cuvette is inserted in the instrument (or, select **4** from the QC Selects menu.)
Notes Menu		Press the **NOTE** key after a cuvette is inserted in the instrument.
ID Selects Menu		Press the **ID** key while a cuvette is inserted in the instrument.
Print/Scan Menu 1		Press the **PRINT/SCAN** key.

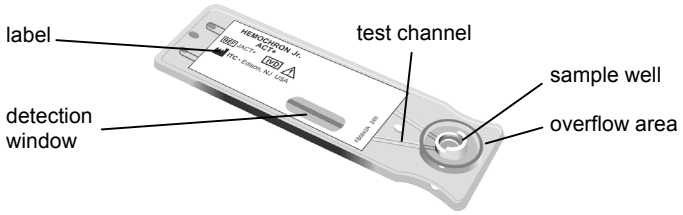
Menu	Commands	Access
Print by Patient Menu		Press the **4** key while the Print Menu 1 is displayed.
Print by QC Menu		Press the **5** key while the Print Menu 1 is displayed.
Print/Scan Menu 2		Press the **7** key while Print Menu 1 is displayed.
Database Menu		Press the **DATABASE** key.

Execute a command on a menu by pressing the action key for that command. For example, if the Main menu is displayed, press the **4** key to shut down the system, or press the **5** key to display system information.

***Note**: The main menu cannot be accessed if a cuvette is in the test well. If a cuvette is used to turn on the instrument, it must be removed to access the main menu.*

Test Cuvettes

Tests are performed with single-use disposable HEMOCHRON Jr. test cuvettes. Each test cuvette contains a **label**, a **sample well**, a **test channel** containing reagents, an enclosed **waste reservoir**, and one or more optical **detection windows**.



The cuvette label is human- and instrument-readable. The current test is automatically read by the instrument and displayed for confirmation when the operator inserts the cuvette into the test chamber. After the cuvette has warmed, **Add Sample** and **Press Start** are displayed by the instrument, alerting the operator to place a drop of blood in the sample well and begin the test by pressing the **START** key.

> ***Note**: Refer to the package insert accompanying the HEMOCHRON Jr. test cuvettes for storage and handling instructions.*

Features

The HEMOCHRON *Signature Elite* has a number of performance and convenience features. These are summarized below:

- the system is portable for bedside use
- fresh whole blood or citrated whole blood can be used (assay dependent)
- only one drop of blood is required
- results are available in minutes
- results are displayed appropriately as whole blood, plasma equivalent, Celite equivalent seconds, or INR
- test type is automatically read from the cuvette
- barcode or manual entry of identification numbers, cuvette lot information, and quality control lot information
- test results are automatically stamped with date and time
- results from 600 patient tests and 600 QC tests can be stored
- stored results can be printed and/or downloaded to a personal computer
- stored results can be printed by Patient ID
- instrument self checks are automatically performed
- internal Electronic Quality Control (EQC) is designed to check instrument operation at two levels
- Electronic Quality Control (EQC) levels selectable for 300 seconds or 500 seconds using HEMOCHRON *Configuration Manager* software
- internal temperature verification is designed to check test chamber temperature
- the display is illuminated for viewing in low light
- the user is alerted when the battery is low
- an optional printer can be connected
- the system can be customized using a personal computer and HEMOCHRON *Configuration Manager* software
- User Notes can be entered to add additional information to the test results
- Patient/QC test reports can be created using a personal computer and ITC data management software programs
- POCT 1A compliant
- Operator certification lockout
- Cuvette expiration lockout
- QC expiration lockout

Instrument Lockouts

The instrument can be configured to allow use only by authorized operators and/or to allow use only if specified QC has been performed. If one or more of these lockouts is enabled, processing of the lockout(s) occurs before any other instrument functions.

Prewarming

If the lockout checks are passed, a cuvette is automatically prewarmed to 37 °C ±1.0 °C when it is placed in the test chamber. The instrument will sound one short beep when pre-warming is complete.

Test Timeout

Incubation of a cuvette stops automatically if **START** is not pressed within five minutes after **Add Sample** and **Press Start** are displayed.

Automatic Shutdown

The instrument will automatically shut down after being idle for five minutes if there is no cuvette inserted in the test chamber and the instrument is running on the battery.

> ***Note**: Results that are greater than the time noted in the package insert for a test are beyond the sensitivity range of the test. They should be repeated immediately and, if confirmed, reported as greater than the maximum sensitivity range.*

IMPORTANT LABELS AND SYMBOLS

Serial Number Label

A serial number label on the rear of the HEMOCHRON *Signature Elite* instrument alerts users to the following:

HEMOCHRON Signature Elite®
Whole Blood Microcoagulation System
SN
IVD
INPUT
12.0 VDC
3.5 AMP
IEC 60825-1 Class 1 laser product; Complies with 21CRR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No.50, dated July 26, 2001.
ITC - 8 Olsen Ave., Edison, NJ 08820
U.S. Pat. Nos.: 5,302,348
HX1100 9/04

1. Barcode scanner contains an IEC 60825-1 Class 1 laser as indicated on the label
2. SN — Serial Number of Device
3. IVD — For *in vitro* Diagnostic Use
4. Attention - Read accompanying documentation or instructions
5. Manufactured date
6. Manufacturer

Other Symbols

Before using the HEMOCHRON *Signature Elite* system, it is essential that the contents of this *Operator's Manual*, any labels on the instrument or its packaging, and instructions accompanying HEMOCHRON Jr. cuvettes are read and understood by the operator. These materials make reference to additional symbols that are explained below:

	Handle with care. Handle and open the container with care.
	Expiration Date of Cuvettes
LOT	Lot Number of Cuvettes
	Do Not Reuse Cuvettes – Single Use Only
	Upper and Lower Temperature Limitations (For Storage or Use)
	Consult Instructions for Use
12.0V⎓ / 3.5A	Input Port for DC Power Cord from AC/DC Power Module - Polarity, VDC and A Input.
RS232	RS232 Output Port for Data Transfer.
Ethernet	Ethernet Output Port for Data Transfer.
	Laser Aperture Label. Alerts the user that a Class 1 laser light is emitted from the aperture. The label is located on the side of the instrument, next to the aperture.

SPECIFICATIONS

Specifications for the HEMOCHRON *Signature Elite* Whole Blood Microcoagulation System are listed below.

Dimensions and Weight

Depth	9.4 cm (3.7 in)
Width	19 cm (7.5 in)
Height	5 cm (2.0 in)
Weight	0.53 kg (1.2 lbs)

Performance

Test Precision	≤ 10% C.V. for whole blood samples

Operation

Test Chamber	1
Timing Range	0 second to 1005 seconds
Incubation Temperature	37 °C ±1.0 °C
Incubation Warm-Up Time	30 seconds to 90 seconds
Full-Charge Operating Time	> 2 hours
Battery Life	500 recharges
Battery Type	Lithium Ion
Throughput (Full Charge)	49 test cycles (at 150 sec per test)
	17 test cycles (> 500 sec per test)
Operating Environment	15 °C to 30 °C

AC/DC Power Module

Input Power	100 to 240 VAC, 50 to 60 Hz
Output Power	12.0 VDC, 3.5 Amps (42 Watts, 144 BTU/hr) minimum

Barcode Reader

Supported Barcode Formats	UPC/EAN, Code 128, Code 39, Trioptic Code 39, Code 93, Interleaved 2 of 5, Discrete 2 of 5, Codabar, and MSI Plessey
Laser Class	IEC 60825-1 Class 1 laser product complies with 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No. 50 dated July 26, 2001
Laser Wavelength	650 nm
Laser Power	0.25 mW

Calibration

The *Signature Elite* instrument is calibrated at the manufacturing facility to test and verify all functions. The instrument is also self-calibrating, as all instrument functions are continuously monitored and verified by the instrument software when a test is performed. The instrument does not require additional calibration by the user.

PREPARING THE INSTRUMENT

Unpacking and Inspection

***Note**: Inspect each component for damage when unpacking. If damage is observed, contact your shipper or service representative immediately.*

1. Remove any protective packaging that may be present around the instrument.
2. Examine the packaging material to be sure that the power supply, connecting cables or other components have been removed. The materials that are provided are listed below.

   ***Note**: Do not discard the packaging material.*

Materials Provided

Article	Quantity
HEMOCHRON *Signature Elite* Microcoagulation Instrument	1
PC Cable (ITC Part No. HJ7405; see *Connecting a Computer or Printer* on page 23)	1
AC/DC Power Module (ITC Part No. HX1025)	1
Operator's Manual	1
HEMOCHRON *Configuration Manager* CD V3.0 or higher	1

***Note:** An AC power cord is provided in the United States, Canada, and Japan.*

Materials Required, But Not Provided

Article	Quantity
HEMOCHRON Jr. Test Cuvettes	As Needed
HEMOCHRON Jr. Quality Control Products	As Needed

Optional Materials

Article	Quantity
HEMOCHRON Jr. PKIT (Printer Kit)	1
HEMOCHRON Jr. PCKIT (Personal Computer Interface Cable)	1
HEMOCHRON Jr. CBL-SIG (Serial Printer Interface Cable)	1
HEMOCHRON *ReportMaker*™ V6.0 or higher CD (Data Management Software)	1
idms V7.2 or higher (Integrated Data Management System)	1

Charging the Battery

The battery of the system should be charged before the system is used.

1. Plug the AC/DC Power Module into an electrical service outlet.
2. Connect the AC/DC Power Module cord to the power connector on the side of the instrument. The charge indicator on the instrument keypad will illuminate.
3. Allow the battery to charge for at least eight hours.

   ***Note**: The AC/DC Power Module can remain connected all the time.*
4. To ensure adequate charge, leave the instrument connected to the charger for a minimum of eight hours. This eliminates the risk of the instrument powering down during a test.

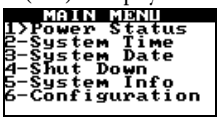
Battery Warnings

The message CHARGE BATTERY is displayed intermittently when the remaining battery power is insufficient to ensure test completion. The message BATTERY FAULT is displayed when the battery is completely discharged and cannot be used to run additional tests. The AC/DC Power Module must be used for additional tests until the battery is recharged.

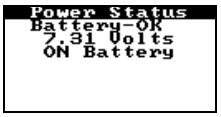
If either the battery voltage or the AC/DC Power Module voltage is too high, the instrument beeps continuously and displays the message DISCONNECT AC ADAPTER IMMEDIATELY. The AC/DC Power Module must be disconnected to shut down the instrument in this condition.

Checking the Battery

1. Press and hold **START** to turn on the instrument.
2. Press **0** (zero) to display the main menu:



3. Press **1**. The battery status is displayed:

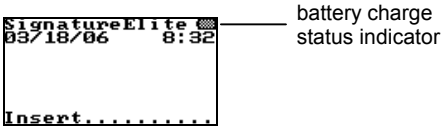


Note: *Battery status is displayed as* ***OK****,* ***LOW****, or* ***BAD****.*

4. Press **CANCEL** twice to return to normal operation.

Battery Charge Indicators

A battery charge LED on the front panel (page 5) is illuminated whenever the battery is being charged. The LED flashes when the remaining battery power is low. A battery charge status indicator is also displayed in the upper right corner of the screen when a system disconnected from the AC/DC Power Module is ready to run a test.



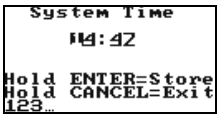
Setting the System Time and Date

The time and date a test is run is saved with the test results. The system time and date can be reset by the operator unless the system is in a lockout condition or the time and date are permanently locked (see the *Configuration Manager* section).

Note*: The date and time can also be set from the Supervisor menu (page 17) or from HEMOCHRON Configuration Manager (page 71). If the unit has been off for an extended period of time or the battery is very weak, the operator will be prompted to enter or verify that the time and date are correct.*

To Set the System Time:

1. Press and hold **START** to turn on the instrument.
2. Press **0** (zero) to display the main menu.
3. Press **2** to display the time:



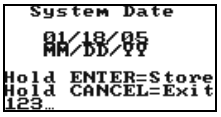
4. Enter the new time using the numeric keys.

   ***Note**: Use the 24-hour format (i.e., enter 15:30 for 3:30 pm). The leading zero is required for single digit times (i.e., enter 06:30 for 6:30 am).*

5. Press and hold down **ENTER**. **Stored** is displayed and the entry is saved.
6. Press **CANCEL** to return to normal operation.

To Set the System Date:

1. Press and hold **START** to turn on the instrument.
2. Press **0** (zero) to display the main menu.
3. Press **3** to display the date:



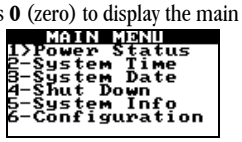
4. Type the new date using the numeric keys.

   ***Note**: Use the US (i.e., **MM/DD/YY**) or the IVDD (i.e., **YY-MM-DD**) date format. The leading zero is required for single digit dates (i.e., enter 06/01/06 for June 1, 2006).*

5. Press and hold down **ENTER**. **Stored** is displayed and the entry is saved.
6. Press **CANCEL** to return to normal operation.

Instrument Shutdown

1. Press **0** (zero) to display the main menu:



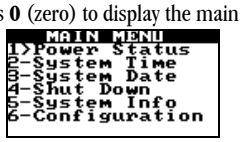
2. Press **4**. The instrument is shut down.

   ***Note**: The instrument can also be shut down by pressing and holding down the **START** key for four seconds. The instrument will automatically shut down after being idle for five minutes if there is no cuvette inserted in the test chamber and the instrument is running on the battery.*

Displaying System Information

The instrument software version, instrument serial number, and other system software information for the HEMOCHRON *Signature Elite* instrument can be displayed.

1. Press and hold **START** to turn on the instrument.
2. Press **0** (zero) to display the main menu:



3. Press **5** to display the system information:

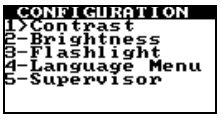
(example only)

   ***Note**: The Main Menu will again be displayed after several seconds, or press **CANCEL** to return to normal operation.*

Configuring Display Brightness, Contrast, and Illumination

The brightness and contrast of the display can be adjusted and the length of time that the display remains illuminated after a test is completed or a key is pressed can be set.

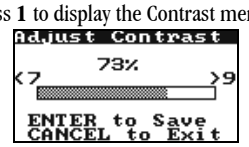
1. Press and hold **START** to turn on the instrument.
2. Press **0** (zero) to display the main menu.
3. Press **6** for the Configuration menu:



To Adjust the Display Contrast:

Display contrast can be set so characters are darker (more contrast) or lighter (less contrast).

1. Press **1** to display the Contrast menu:



2. Press **7** to decrease the contrast. Press **9** to increase the contrast.

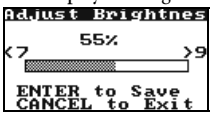
   ***Note**: Pressing and holding a key for more than one second will cause it to auto-repeat.*

3. Press **ENTER** to save the new setting.

To Adjust the Display Brightness:

Display brightness can be set so the display background is darker or lighter.

1. Press **2** to display the Brightness menu:



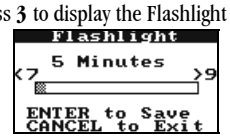
2. Press **7** to decrease the brightness. Press **9** to increase the brightness.

   ***Note**: Pressing and holding a key for more than one second will cause it to auto-repeat.*

3. Press **ENTER** to save the new setting.

To Adjust the Length of Time the Display Remains Illuminated:

1. Press **3** to display the Flashlight menu:



2. Press **7** to decrease the length of time the display remains illuminated. Press **9** to increase the time.

   ***Note**: Pressing and holding a key for more than one second will cause it to auto-repeat.*

   ***Note**: The factory default time for display illumination is five minutes. The maximum illumination time is 100 minutes. To disable display illumination, set the time to zero (**0**).*

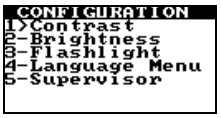
3. Press **ENTER** to save the new setting.

Displaying Available Languages

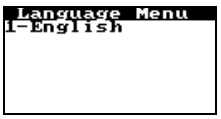
English is the only language that is available in HEMOCHRON *Signature Elite* software. Additional languages will be available in future software versions.

To Display the Menu of Available Languages:

1. Press and hold **START** to turn on the instrument.
2. Press **0** (zero) to display the main menu.
3. Press **6** for the Configuration menu:



4. Press **4** to display the menu of available languages:



5. Press the numeral key that corresponds to the language to be used.
6. Press **ENTER** to save the new setting.

Supervisor Functions

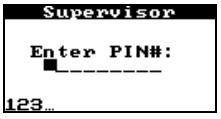
The Supervisor menu allows additional actions to be carried out by the laboratory supervisor:

- Scan cuvette or quality control material barcodes to upload the lot number, expiration date, and expected range (for control materials) to HEMOCHRON *Configuration Manager*
- Scan Operator IDs for uploading to HEMOCHRON *Configuration Manager*
- Set the instrument date and time (this can also be done from the main menu)
- Print listings of cuvette lot numbers, quality control lot numbers, or Operator IDs
- Set the instrument baud rate
- Enter communication parameters

To Access the Supervisor Functions:

1. Press and hold **START** to turn on the instrument.
2. Press **0** (zero) to display the main menu.
3. Press **6** for the Configuration menu:

4. Press **5**. A prompt is displayed to enter the Supervisor PIN:

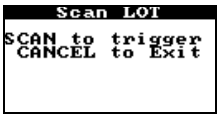


***Note**: The Supervisor PIN is set using HEMOCHRON Configuration Manager (see page 54). If an instrument does not yet have a Supervisor PIN, press and hold the **ENTER** key at the prompt.*

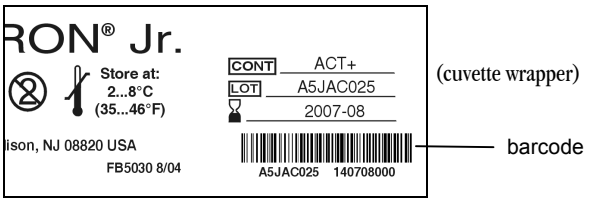
5. Enter the Supervisor PIN, then press and hold the **ENTER** key. The Supervisor menu is displayed:

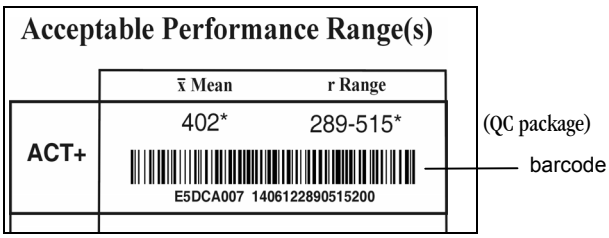
Scanning Lot Information for Cuvettes or Quality Control Materials

1. On the Supervisor menu, press **1** to display the Scan Lot screen:



2. Hold the instrument over the barcode on the cuvette wrapper or QC package:





Note: Position the scanner port of the instrument approximately four inches from the barcode (see page 5).

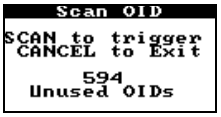
3. Press **PRINT/SCAN** to scan the barcode label. The scanned lot number and a **Stored** confirmation message are displayed, and the entry is saved.

   Note: *Additional lots can be scanned by repeating Steps **2** and **3**.*

4. Press **CANCEL** to exit.

Scanning Operator IDs

1. On the Supervisor menu, press **2** to display the Scan OID screen:



2. **Position the scanner port of the instrument approximately four inches from the barcode** (see page 5).
3. Press **PRINT/SCAN** to scan the barcode. The scanned Operator ID and a **Stored** confirmation message are displayed, and the entry is saved.

   Note: *Additional Operator IDs can be scanned by repeating Steps **2** and **3**.*

4. Press **CANCEL** to exit.

Setting the System Time or System Date

For convenience, the Supervisor menu includes the same commands that are on the main menu for changing the system time and system date.

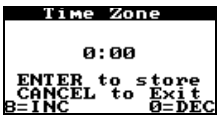
1. On the Supervisor menu, press **3** to set the system time.
2. On the Supervisor menu, press **4** to set the system date.

   Note: *Procedures for setting the system time and system date are described on page 14.*

Specifying the Time Zone

The time zone setting is used to compare the instrument time to Greenwich Mean Time (GMT). This allows the instrument to communicate with other devices in accordance with CLSI Standard POCT-1A.

1. On the Supervisor menu, press **5** to display the Time Zone screen:



2. Enter the difference (in hours and minutes) between the local time zone and GMT. For example, if the local time is 2:00 pm and GMT is 7:00 pm, enter **–5.00**.

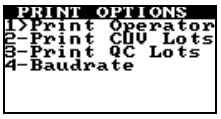
   ***Note**: Press the **8** key to enter positive (+) time differences in 15-minute increments. Press the **0** key to enter negative (-) time differences in 15-minute increments.*

3. Press **ENTER** to store the time zone.
4. Press **CANCEL** to exit.

Specifying Print Options

Listings of cuvette lot numbers, quality control lot numbers, or Operator IDs can be printed at an external printer (see page 23 for instructions to connect the printer).

1. On the Supervisor menu, press **6** to display the Print Options menu:

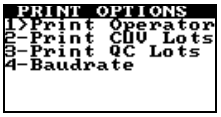


2. Press **1** to print a listing of Operator IDs.
3. Press **2** to print a listing of cuvette lot numbers.
4. Press **3** to print a listing of quality control material numbers.

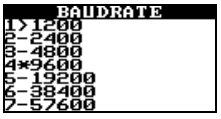
Specifying the Baud Rate

Listings of cuvette lot numbers, quality control lot numbers, or Operator IDs can be printed at an external printer (see page 23 for instruction to connect the printer).

1. On the Supervisor menu, press **6** to display the Print Options menu:



2. Press **4** to display the Baud Rate screen.



3. Press the numeral key that corresponds to the baud rate to be selected.

   ***Note**: The baud rate that is currently specified is designated by an asterisk (*).*

4. Press **CANCEL** to exit.

Specifying the Communication Protocol

The instrument can communicate with a personal computer (using the COM port) or a network (using the Ethernet port). One of two communication protocols can be selected:

- An ITC proprietary communication protocol that allows records to be transferred from the instrument and allows the instrument to be configured using ITC software such as HEMOCHRON *Configuration Manager*.
- A communication protocol that meets CLSI POCT-1A standards. This protocol allows the instrument to communicate with any software or device that is compliant with POCT-1A.

***Note**: If the CLSI POCT-1A compliant communication protocol is used, communication must be initiated from the instrument. If the ITC proprietary communication protocol is used, communication must be initiated from either the personal computer or the network.*

1. From the Supervisor menu, press **7** to display the Communications menu:

2. Press **1** to select the desired communication protocol. (Display **OFF** to use the ITC proprietary communication protocol, or display **ON** to use the CLSI POCT-1A compliant communication protocol.)

   ***Note**: Specifying POCT connectivity acts as a toggle. If CLSI POCT-1A connectivity standards are already specified (**POCT ON** is displayed), this can be cancelled by pressing **1** again to display **POCT OFF**.*

Specifying the Communication Port

1. From the Supervisor menu, press **7** to display the Communications menu:

2. Press **2** to select the desired port. (Display **COM** to specify use of the COM port, or display **NET** to specify use of the Ethernet port.)

   ***Note**: Specifying the port acts as a toggle. If use of the Ethernet port is already specified (**Port NET** is displayed), this can be cancelled by pressing **2** again to display **Port COM**.*

Specifying Continuous POCT-1A Communication

***Note**: Communication is initiated from the instrument only when the CLSI POCT-1A compliant communication protocol is used. If the ITC proprietary communication protocol is used, communication is initiated from a personal computer or network.*

1. From the Supervisor menu, press **7** to display the Communications menu:

2. Press **3** to select the desired communication option when the CLSI POCT-1A compliant communication protocol is used. (Display **OFF** to initiate communication only if requested, or display **ON** to initiate continuous communication whenever the instrument is started.)

   ***Note**: Specifying the communication option acts as a toggle. If initiation of communication upon startup is already specified (**Push POCT ON** is displayed), this can be cancelled by pressing **3** again to display **Push POCT OFF**.*

Entering Network Communication Parameters

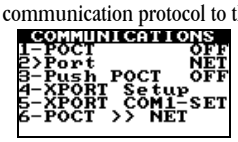
Some or all of the following parameters may need to be entered in order for the instrument to communicate over a network:

- IP Address
- Gateway
- NetMask
- Remote IP
- Remote Port

***Note**: Consult with the network administrator for your facility to determine which parameters must be entered and what those settings should be.*

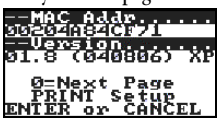
1. From the Supervisor menu, press **7** to display the Communications menu:

2. (If the CLSI POCT-1A compliant communication protocol is currently selected): Press **1** to toggle the communication protocol to the ITC proprietary communication protocol:



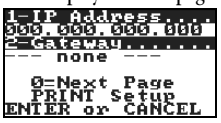
***Note**: The CLSI POCT-1A compliant communication protocol must be **OFF** when running XPORT Setup.*

3. Press **4** to start the XPORT Setup module. The message **XPORT Setup Please Wait** is displayed, followed by the first page of the XPORT Setup module:

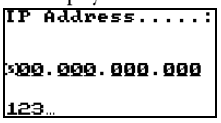


***Note**: If the message **XPORT Setup NOT RESPONDING!** is displayed, contact ITC Technical Support at (800) 631-5945 or (732) 548-5700, or by e-mail at techsupport@itcmed.com.*

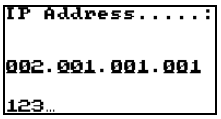
4. Press **0** to display the next page (for entering IP Address and Gateway settings):



5. Press **1** to display the screen for entry of the IP Address:



Enter the IP Address using the numeral keys:



***Note**: Press **Enter** to move to the next field without entering a numeral. Press **Cancel** to move to the previous field.*

6. After the IP Address has been entered, press and hold **ENTER.** The message **Parameter String Stored** is displayed, followed by the screen for entering IP Address and Gateway settings:

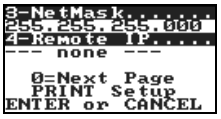
***Important**: The parameter string is temporarily stored. Even though the new parameter is displayed on the screen, it is not saved until **Enter** is pressed to exit XPORT Setup (Step 13).*

***Note**: A range of IP addresses (from **169.254.0.1** to **169.254.255.1**) has been reserved for Auto-IP enabled devices. This range of Auto IP addresses should not to be used over the Internet.*

*Auto-IP can be disabled by setting the device's IP address to **000.000.001.000**. This setting enables DHCP but disables Auto-IP.*

7. Press **2** to display the screen for entry of the Gateway. Enter the Gateway in the same manner as for the IP Address, then press and hold **ENTER** to again display the screen for entering IP Address and Gateway settings.

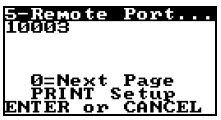
8. Press **0** to display the next page (for entering NetMask and Remote IP settings) of the XPORT Setup module:



9. Press **3** to display the screen for entry of the NetMask. Enter the NetMask in the same manner as for the IP Address, then press and hold **ENTER** to again display the screen for entering NetMask and Remote IP settings.

10. Press **4** to display the screen for entry of the Remote IP. Enter the Remote IP in the same manner as for the IP Address, then press and hold **ENTER** to again display the screen for entering NetMask and Remote IP settings.

11. Press **0** to display the next page (for entering the Remote Port setting) of the XPORT Setup module:



12. Press **5** to display the screen for entry of the Remote Port. Enter the Remote Port in the same manner as for the IP Address, then press and hold **ENTER** to again display the screen for entering the Remote Port setting.

13. Press **ENTER** while any page of the XPORT Setup module is displayed to save the new parameters. The message **Updating XPORT** is displayed, followed by the Communications menu (see Step 1).

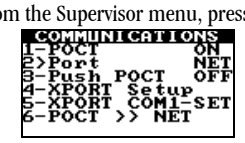
***Important**: Parameters are temporarily stored until the **Enter** key is pressed while any page of the XPORT Setup module is displayed. If the **Cancel** key is pressed while any page of the XPORT Setup module is displayed, the message **Cancel without updating XPORT?** is displayed for confirmation by the operator.*

***Note**: The parameters can be printed to a device connected to the COM port by pressing the **PRINT/SCAN** key.*

Configuring Network Communication Parameters Using a Personal Computer

An experienced network administrator can communicate with the XPORT Setup module and enter communication parameters using a personal computer connected to the COM port.

1. From the Supervisor menu, press **7** to display the Communications menu:



2. (If the CLSI POCT-1A compliant communication protocol is currently **ON**): Press **1** to toggle **ON** to **OFF** for the ITC proprietary communication protocol:

***Note**: The CLSI POCT-1A compliant communication protocol must be **OFF** when running XPORT Setup.*

3. Press **5** to start the XPORT COM-1 Setup module. The message **XPORT Setup Please Wait** is displayed, followed by the message **XPORT COM1-SET**.

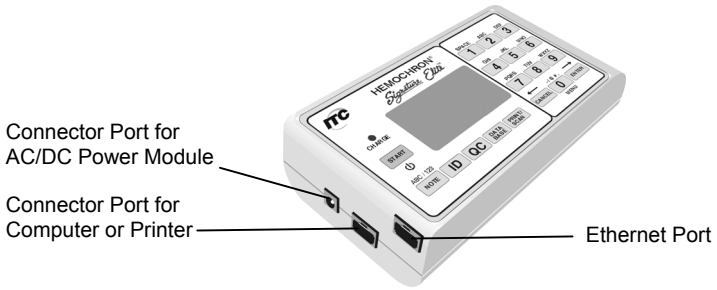
   The XPORT module can now communicate with the personal computer through the COM port, using terminal emulator software such as Microsoft Windows Hyperterminal.

   ***Note**: Description of XPORT Setup menus and commands using terminal emulator software is beyond the scope of this Operator's Manual. If needed, contact ITC Technical Support for assistance at (800) 631-5945 or (732) 548-5700, or by e-mail at techsupport@itcmed.com.*

4. Upon completing the communication session, press **Cancel** to exit the session and display the Communications menu again.

Connecting a Computer or Printer

An IBM-compatible laboratory computer or a serial printer (Seiko DPU-414 is recommended) can be used with the system. The connector port for these devices is located at the side of the instrument.



To Connect to a Printer:

1. Obtain a printer interface cable.

   ***Note**: The printer interface cable is included with the optional HEMOCHRON Jr. PKIT (Printer Kit) only. A separate CBL-SIG (Serial Printer Interface Cable) can be obtained from ITC, or a cable can be prepared as outlined below. If a printer is connected, the serial printer communication parameters must be set to 9600 baud with no parity, 8 data bits and 1 stopbit using XON/XOFF 3-wire software protocol. For additional information on printer configuration, contact ITC Technical Support at **(800) 631-5945** or **(732) 548-5700**, or by e-mail at techsupport@itcmed.com.*
2. Connect one end of the cable to the printer connector port on the side of the instrument.
3. Connect the other end of the printer cable to the printer.

To Connect to a Personal Computer:

1. Obtain a computer interface cable.

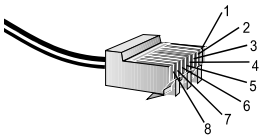
   ***Note:** The computer interface cable is included with the instrument. A replacement PCKIT (Personal Computer Interface Cable) can be obtained from ITC, or a cable can be prepared as outlined below. Contact ITC Technical Support for instructions on setting up the personal computer.*
2. Connect one end of the cable to the computer connector port on the side of the instrument.
3. Connect the other end of the cable to an unused serial communication port on the computer.

To Connect to a Network:

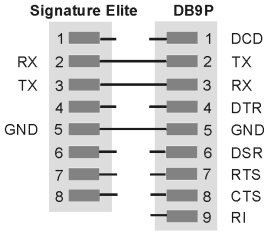
1. Obtain a network interface cable.
2. Connect one end of the cable to the Ethernet port on the side of the instrument.
3. Connect the other end of the cable to a network connection port.

Preparing a Printer or Computer Interface Cable

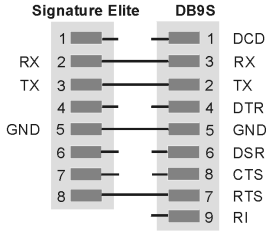
Cabling and connectors can be purchased locally at an electronics store. Use an 8-wire RJ45 to RJ45 modular straight through connecting cable (no longer than 25 feet) plus an RJ45 to DB9 adapter. Numbering of the pins on the RJ45 connectors is shown below:



The cable configurations used for connecting a serial printer or a computer are shown below:



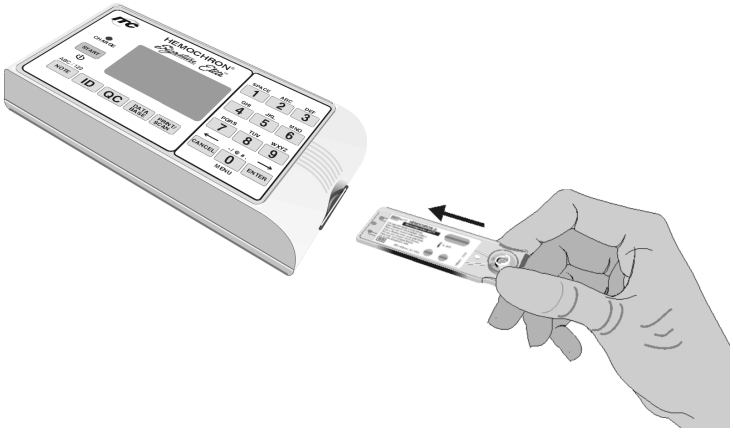
Connecting the instrument to the Seiko DPU-414 printer with a DB9S connector



Connecting the instrument to any personal computer with a DB9P connector

STARTING THE INSTRUMENT

Start the instrument by pressing and holding down the **START** key or by inserting a cuvette:

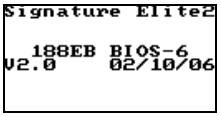


***Note**: Allow cuvettes to reach room temperature (15 to 30 °C) before opening the pouch. This may take up to 60 minutes. Consult the cuvette package insert for additional information concerning cuvette storage and handling.*

***Note**: Insert the cuvette with the label facing up. Push the cuvette all the way in until it stops.*

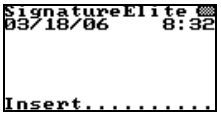
Starting the Instrument by Pressing the START Key

1. When the **START** key is pressed, the following screens are briefly displayed:

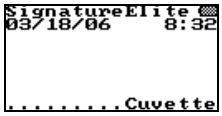


and

2. The instrument then prompts the user that the instrument is ready to accept a cuvette:



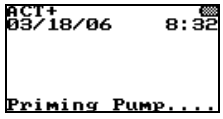
and



Starting the Instrument by Inserting a Cuvette

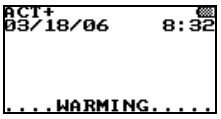
1. When a test cuvette (e.g., ACT+) is inserted to turn on the instrument, the following prompts are briefly displayed:

(example only)
followed by

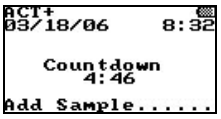


***Note**: The test name for the inserted cuvette is displayed in the upper left-hand corner of the screen. Check the display for fault messages while the cuvette is warming. Refer to the Troubleshooting section for the procedure to resolve a fault message.*

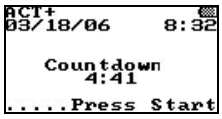
2. The instrument then warms the cuvette to 37 °C ±1.0 °C:



3. When the cuvette reaches temperature, the instrument beeps and alternately displays:



and



4. The sample can now be added. After the sample is added, press **START** to run the test.

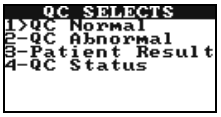
RUNNING A TEST

Samples are designated as patient samples by default. If a control is being run, the sample type must be changed from **patient sample** to **QC Normal** or **QC Abnormal**. If a patient sample is being run, this step is unnecessary.

***Important**: Failure to select **QC Normal** or **QC Abnormal** for a control sample will result in storage of the control results as patient results in the patient database.*

Designating the Sample as a Normal or Abnormal Control

1. Press **QC** to display the QC SELECTS menu:



***Note:** A cuvette must be inserted into the instrument to display the QC SELECTS menu. If entry of a cuvette lot number and/or Operator ID or PIN is required, this must be done before the QC SELECTS menu can be displayed.*

2. Press **1** to designate the sample as a **normal control** (**QC Normal** is displayed), or press **2** to designate the sample as an **abnormal control** (**QC Abnormal** is displayed).

***Note:** The sample type can be designated either before or during the test, unless QC lockout features are enabled. Once **QC** is selected, pressing the **QC** key again briefly displays the QC level and assay being run.*

To exit the QC menu, press the CANCEL key.

Important: Once a QC type is selected, it cannot be changed.

Entering an Optional Patient ID (PID) and/or an Operator ID (OID)

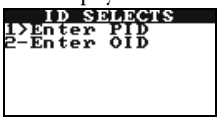
A Patient ID (PID) and/or an Operator ID (OID) can be entered for each test. The IDs will be stored with the test results. Entry of a PID and/or OID is optional unless a mandatory entry is specified (see the *Configuration Manager* section on page 55).

The PID and OID can either be read from a barcode label using the internal barcode scanner or can be entered using the keypad (unless entry of PID and OID by barcode scanning is specified in *Configuration Manager*). Any leading or trailing spaces will be ignored when scanned.

***Note**: Any PID or OID that is manually entered or accepted for Reuse will be flagged as a manual entry in the database. Backspace and overwrite characters as needed, or backspace to the first entry and then backspace twice to clear all entries.*

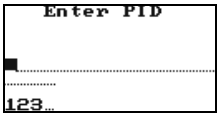
To Enter a Patient ID:

1. Select **ID** to display the ID SELECTS menu:



Note: *A cuvette must be inserted into the instrument to display the ID SELECTS menu.*

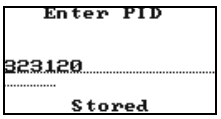
2. Press **1** to display the screen for entering the PID:



Note: *An acceptable PID is any combination of **1** to **20** characters. During PID entry, a PID exceeding 16 characters will wrap to the next line. The number of characters to be entered for PID (from **1** to **20**) may be designated via Configuration Manager. An acceptable range of PID lengths may also be designated. Check the PID by pressing **ID** and then pressing **1** to display the entered value.*

3. Scan the PID from a barcode label using the internal barcode scanner, or enter it using the numeric keys.

   a. To scan the PID from a barcode label, **position the scanner port approximately four inches from the barcode label** (see page 5) and then press **PRINT/SCAN**. The scanned PID and a **Stored** confirmation message are displayed:



   b. To enter the PID manually, type the PID using the keypad and then press and hold **ENTER**. The entered PID and a **Stored** confirmation message are briefly displayed as shown above.

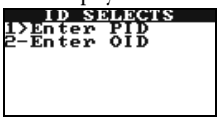
   Note: *Numeric and/or alphabetic characters can be entered. Press the **NOTE** key to change from numeric to alphabetic characters or vice versa.*

   If alphabetic characters are being entered, advance from the displayed letter to the next letter on that key by pressing the key again before the cursor advances.

   Note: *The PID can be designated (or changed) anytime. Check the PID by pressing **ID** and then pressing **1** to display the entered value.*

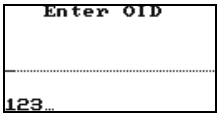
To Enter an Operator ID:

1. Select **ID** to display the ID SELECTS menu:



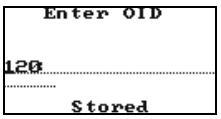
Note: *A cuvette must be inserted into the instrument to display the ID SELECTS menu.*

2. Press **2** to display the screen for entering the OID:



3. Scan the OID from a barcode label using the internal barcode scanner, or enter it using the keypad.

   a. To scan the OID from a barcode label, **position the scanner port approximately four inches from the barcode label** (see page 5) and then press **PRINT/SCAN**. The scanned OID and a **Stored** confirmation message are displayed:



   b. To enter the OID manually, type the OID using the keypad and then press and hold **ENTER**. The entered OID and a **Stored** confirmation message are displayed as shown above.

   Note: *Up to 16 numeric and/or alphabetic characters can be entered. Press the **NOTE** key to change from numeric to alphabetical characters or vice versa.*

   If alphabetic characters are being entered, advance from the displayed letter to the next letter on that key by pressing the key again before the cursor advances.

   Note: *The OID can be designated (or changed) anytime unless operator lockout is enabled through Configuration Manager. Check the OID by pressing **ID** and then pressing **2** to display the entered value.*

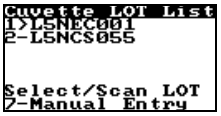
Entering a Mandatory Cuvette Lot Number and Expiration Date

Entry of the cuvette lot number and expiration date can be required for completion of a test.

***Note**: Prompts for entry of cuvette lot information are only displayed if the appropriate cuvette lot option is enabled through Configuration Manager (see page 55). If **Required**, **Scan Only**, and/or **Pre-stored Only** are selected as a cuvette lot option, the corresponding prompts to enter the information are automatically displayed. If none of the cuvette lot options are selected, there is no other means for cuvette lot information to be entered.*

To Enter Mandatory Cuvette Information:

1. The prompt to enter a cuvette lot number is automatically displayed when a cuvette is inserted:



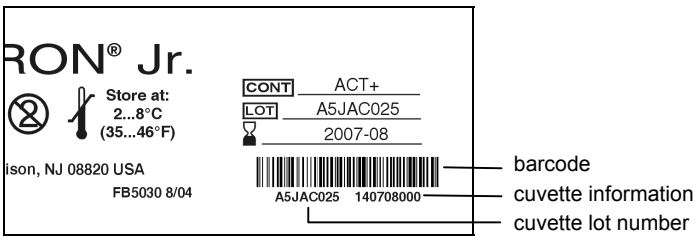
2. Select the cuvette lot number from the list, scan the cuvette lot number, or enter it using the keypad.

   a. To select the cuvette lot number from the list, press the numeral key for that lot number. For example, press **2** to select lot number **L5NCS055** in the example above.

   ***Note**: Information for up to five lots of cuvettes for each assay type can be scanned using the Supervisor menu (page 17) or entered using Configuration Manager (see page 63). A cuvette lot number that has been scanned or entered is not displayed on the list after the lot reaches its expiration date.*

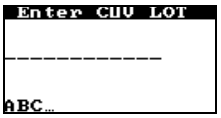
   ***Note**: If more than five cuvette lot numbers per assay are scanned or entered, the lot number(s) with the closest expiration date will be deleted.*

b. To scan the cuvette lot number and information, **position the scanner port approximately four inches from the barcode** (see page 5) on the cuvette wrapper and then press **PRINT/SCAN**.

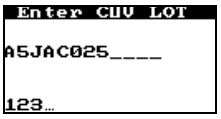


The scanned lot number and **Stored** are displayed.

c. To enter the cuvette lot number and information manually, press **7** to display the screen for entering the cuvette lot number:



Enter the cuvette lot number using the numeral keys:



Note: *Press the **NOTE** key to change from numeric to alphabetical characters or vice versa. When alphabetic characters are being entered, advance from the displayed letter to the next letter on that key by pressing the key again before the cursor advances.*

Note*: Cuvette lot numbers that are manually entered into the HEMOCHRON Signature Elite instrument are only saved to the current test record. They are not uploaded to Configuration Manager.*

After the cuvette lot number has been entered, press and hold **ENTER** to display the screen for entering the cuvette information:

Enter the cuvette information using the numeral keys:

Note*: The cuvette information field contains an encoded expiration date (**140708000** in the example).*

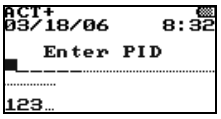
After the cuvette information has been entered, press and hold **ENTER** to continue with the test.

Entering a Mandatory PID and/or OID or PIN

Entry of a Patient ID (PID) and/or an Operator ID (OID) or Operator Personal Identification Number (PIN) can be required for completion of a test (see the *Configuration Manager* section on page 55). If entry of one or more of these IDs is required, appropriate prompts for entry of PID and/or OID or PIN are automatically displayed.

To Enter a Mandatory Patient ID:

1. The PID prompt is automatically displayed when a cuvette is inserted (or after a mandatory cuvette lot and/or OID is entered):



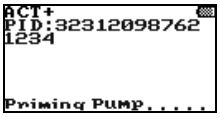
Note: *The dashed line after the cursor denotes the minimum length of the PID, The dotted line following the dashed line denotes the maximum length of the PID (if specified in Configuration Manager).*

Note: *Pressing the **QC** button after the PID prompt is displayed allows a QC test to be performed. Entry of a PID is not required in this case.*

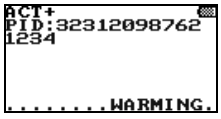
2. Scan the PID from a barcode label using the internal barcode scanner, or enter it using the keypad.

Note: *Refer to Step 3 on page 27 for the procedure to scan the PID using the barcode scanner or to enter it manually.*

3. Press and hold **ENTER**. If an acceptable PID is entered, operation of the instrument continues:



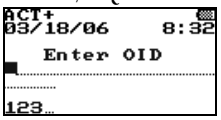
followed by



Note: *When running a test or viewing results, a PID exceeding 11 characters will wrap to the next line.*

To Enter a Mandatory Operator ID:

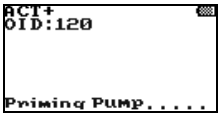
1. The OID prompt is automatically displayed when a cuvette is inserted (or after a mandatory cuvette lot and/or QC lot is entered):



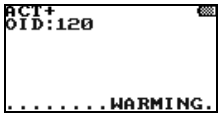
2. Scan the OID from a barcode label using the internal barcode scanner, or enter it using the keypad.

Note: *Refer to Step 3 on page 28 for the procedure to scan the OID using the barcode scanner or to enter it manually.*

3. Press and hold **ENTER**. If an acceptable OID is entered, operation of the instrument continues:



followed by



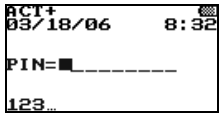
Note: *If entry of any OID is specified, an acceptable OID is any number up to 16 digits. If entry of a valid OID is specified, an acceptable OID is any number contained in the Operator Table (see page 61).*

*Check the OID by pressing **ID** and then pressing **2** to display the entered value.*

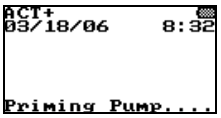
4. If an unacceptable OID is entered, **ID is Not Valid** is displayed followed by the OID prompt. Operation of the instrument will not continue until an acceptable OID is entered.

To Enter a Mandatory Operator PIN:

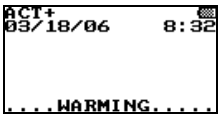
1. The PIN prompt is automatically displayed when a cuvette is inserted:



2. Enter the PIN using the keypad.
3. Press and hold **ENTER**. If an acceptable PIN is entered, operation of the instrument continues:



followed by



Note: *An acceptable PIN is any string of up to nine numeric digits (other than* ***0****) that matches a PIN in the Operator Table.*

4. If an unacceptable PIN is entered, **ID is Not Valid** is displayed followed by the PIN prompt. Operation of the instrument will not continue until an acceptable PIN is entered.

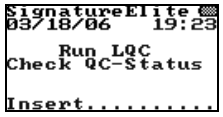
Prompts for Mandatory QC Tests

Electronic quality control (EQC) tests and/or liquid quality control (LQC) tests can also be required to be run at specified intervals (see the *Configuration Manager* section). When it is time for a required QC test to be run, the required QC test must be successfully completed before the specific patient test(s) can be run. If EQC is required, no patient tests can be run until successful completion of EQC.

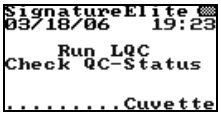
Note*: A specified limited number of additional tests per assay (****911 exceptions****) can be run after a mandatory QC interval has been reached.* ***Successful QC tests for an assay will automatically reset the 911 exception for that assay.*** *Consult the Configuration Manager section for details.*

To Run a Mandatory QC Test:

1. After a specified QC interval (see page 57 in the *Configuration Manager* section) passes without a successful QC test, a prompt to run the required QC test is automatically displayed:

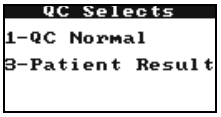


and



2. Press the **QC** key to display additional information concerning QC testing that is required (REQ):

3. If a cuvette is inserted for a test with an expired QC interval, the message **LQC Expired** is displayed, followed by a prompt to run either a QC test or another patient sample (if the number of 911 Exceptions has not been exceeded):



4. Run the QC test according to the displayed prompts. If the results for the QC test are acceptable, patient tests can now be run.

Entering a Mandatory Lot Number, Expiration Date, and Expected Range for Controls

Entry of the lot number, expiration date, and expected range of liquid controls can be required for completion of a QC test.

***Note**: Prompts for entry of the lot number, expiration date, and expected range of liquid controls are only displayed if the appropriate QC lot option is enabled through Configuration Manager (see page 56). If **Required**, **Scan Only**, and/or **Pre-stored Only** are selected as a QC lot option, the corresponding prompts to enter the information are automatically displayed. If none of the QC lot options are selected, there is no other means for QC lot information to be entered.*

To Enter Mandatory Control Information:

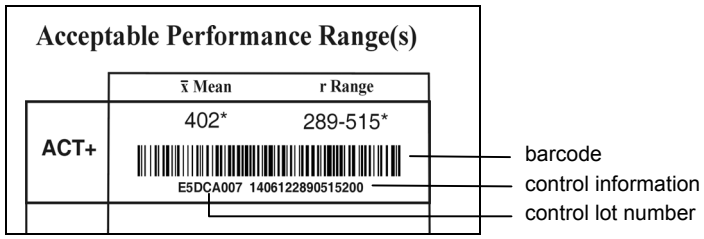
1. The prompt to enter a QC lot number is automatically displayed when a QC test is selected:

2. Select the QC lot number from the list, scan the control lot number, or enter it using the keypad.

   a. To select the QC lot number from the list, press the numeral key for that lot number. For example, press **1** to select lot number **E5DCA007** in the example above.

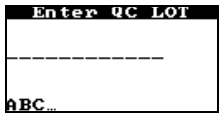
   ***Note**: Information for each lot of controls is entered using Configuration Manager (see page 64). Information for up to five lots of normal controls and five lots of abnormal controls can be stored for each assay type. A control lot number that has been scanned or entered is not displayed on the list after the lot reaches its expiration date.*

   b. To scan the control information, **position the scanner port approximately four inches from the barcode** (see page 5) on the liquid control packaging and then press PRINT/SCAN.

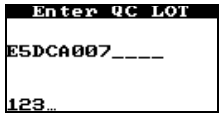


   The scanned lot number and **Stored** are displayed.

   c. To enter the QC lot number and information manually, press **7** to display the screen for entering the QC lot number:



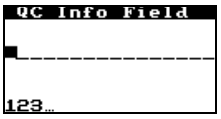
   Enter the QC lot number using the numeral keys:



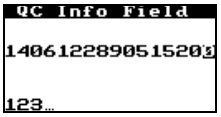
   ***Note:** Press the **NOTE** key to change from numeric to alphabetical characters or vice versa. When alphabetic characters are being entered, advance from the displayed letter to the next letter on that key by pressing the key again before the cursor advances.*

***Note**: QC lot numbers that are manually entered into the HEMOCHRON Signature Elite instrument are only saved to the current test record. They are not uploaded to Configuration Manager.*

After the QC lot number has been entered, press and hold **ENTER** to display the screen for entering the QC information:



Enter the QC information using the numeral keys:



***Note**: The QC information field consists of numerical characters (**1406122890515200** in the example). The expiration date and expected range of the control is encoded in the QC information.*

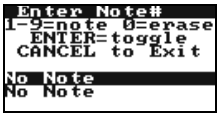
After the QC information has been entered, press and hold **ENTER** to continue with the test.

Adding a Note

Up to two operator-selectable notes can be added to the record for each test and will be printed with the final record. The notes are selected from a menu of nine available notes.

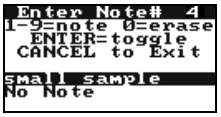
***Note**: Consult the Configuration Manager section for the procedure to add new user-selectable notes to the Note Table.*

1. Press **NOTE**:

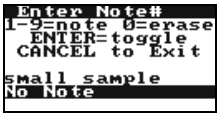


***Note:** A cuvette must be inserted into the instrument before a note can be entered.*

2. Type a number (**1** through **9**) to display the corresponding note in the first note field. For example:



3. To enter a note in the second note field, press **ENTER** to highlight the second note field before typing a number for the second note:



***Note: No Note** is displayed if a note is not defined for a note field. To remove a currently entered note, highlight the note field and enter **0** to display **No Note**.*

***Note:** If a third note is entered, the first note is cancelled.*

4. Press **CANCEL**. The selected note (or notes) are entered into the test record.

Specimen Collection

Collect blood specimens according to CLSI document H21-2, entitled *Collection, Transport and Processing of Blood Specimens for Coagulation Testing and General Performance of Coagulation Assays*.

***Important**: Collect blood specimens in a manner that prevents contamination with tissue thromboplastin, indwelling intravenous (I.V.) solutions, or alcohol cleansing solution. Discard samples that are not properly collected or contain visible clots or debris.*

Use a 23 gauge or larger needle if a syringe is used for blood collection. If a sample is expelled through the same needle, do it slowly to prevent hemolysis.

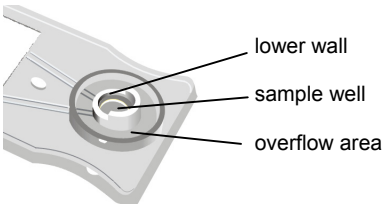
Consult the cuvette package insert for additional information concerning specimen collection and storage.

Starting the Test

After initialization is completed the instrument beeps once, signaling the instrument is ready for the sample. **Add Sample** and **Press Start** are displayed with a countdown to START TIMED OUT (see the note below), and the blood sample can be placed into the cuvette and the test started.

***Note**: START TIMED OUT is displayed if the test is not started within five minutes. If this occurs, repeat the test using a new cuvette.*

1. Place a drop of blood into the sample well of the cuvette:



***Note**: Fill the sample well from the bottom up. Add enough blood so that the lower wall of the center sample well is completely filled. If the meniscus of the blood sample extends above the wall, push the excess blood into the overflow area. A transfer needle can be used to transfer blood.*

2. Press the **START** key. The elapsed time (in seconds) is displayed until the sample clots.

   ***Note**: SAMPLE TOO SMALL, SAMPLE TOO LARGE, or SAMPLE NOT SEEN is displayed if an incorrect amount of sample was added. Repeat the test using a new cuvette.*

3. When a clot is detected, the instrument beeps once. Final results of the test are calculated and displayed.

   ***Note**: The whole blood clotting times are converted to plasma equivalent values (for APTT and APTT Citrate), or plasma equivalent values and International Normalized Ratio (for PT and PT Citrate). Celite equivalent values are displayed for ACT+ and ACT-LR.*

4. Remove the cuvette and discard it.

   ***Note**: Results are saved in the database and printed if a printer is connected. The date and time of the test, cuvette lot and/or QC lot information, PID, OID, note(s) (if entered), and error message (if a fault is detected for the test or sample) are printed with the test result.*

QUALITY CONTROL (QC)

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and other regulatory agencies recommend that medical and laboratory instrumentation be enrolled in a quality assurance program adequate in maintaining accurate and reliable performance of the equipment. Complete records of such quality control must be kept.

Routine quality control testing should be part of a comprehensive quality assurance program. Quality control testing of the HEMOCHRON *Signature Elite* consists of the following operations:

- Testing system performance and verifying system temperature using internal Electronic System Verification every eight hours of operation.
- Testing cuvettes in accordance with the Package Insert for each assay using two levels of liquid controls.

Self-Check

The HEMOCHRON *Signature Elite* instrument performs a "self-check" every time it is activated and a test is performed. When a test is initiated by inserting a cuvette, system checks are automatically performed and include:

- Verification of adequate battery power to complete a full test.
- Verification of the test type on the screen display to insure that the LEDs used for identifying the test are functioning properly.
- Verification that the cuvette temperature is warmed to 37 °C ±1.0 °C. If this temperature is not achieved or is exceeded, an appropriate error message will be displayed and testing is prohibited.
- Verification that the sample is present and is of sufficient size to run test. This insures that the pumps and sample sensing LEDs are functioning properly and that the cuvette is adequately sealed. If these instrument and sample parameters are not appropriate, the test is terminated and an error message displayed.
- Verification that the internal timers function correctly for each test. If the system timer and assay timer disagree, a real-time clock error message is displayed and the test result is not reported.

Verification of Instrument Temperature

Instrument temperature is automatically checked whenever EQC is carried out. The instrument temperature check verifies that a temperature of 37 °C ±1.0 °C is maintained during the test.

> ***Note:*** *If the temperature reading is out of range, please contact ITC Technical Support at* ***(800) 631-5945*** *or* ***(732) 548-5700.***

QC of Instrument Performance

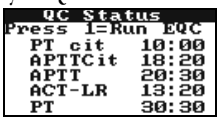
The instrument should be tested at two levels once every eight hours of operation. Automatic internal Electronic Quality Control (EQC) can be used to provide a two-level electronic verification of instrument performance, or liquid quality control products can be used.

> ***Note:*** *HEMOCHRON Configuration Manager is used to specify Automatic EQC, to specify the required interval for performing EQC, and to program EQC Level 2 for either 300 seconds or 500 seconds (see page 58).*
>
> ***Important****: If Auto EQC is selected, ensure that cuvettes are routinely removed from the instrument after completing a test. If EQC is run while a cuvette is inserted, the message* ***Detector Blocked*** *is displayed and the EQC test fails.*

EQC is performed automatically if Automatic EQC is specified and if the HEMOCHRON *Signature Elite* instrument is plugged into the AC/DC Power Module. EQC results are stored to the database and displayed for five minutes (or until **Cancel** is pressed).

QC Using EQC:

1. Display the QC Status menu:



Note: *Display the QC Status menu by pressing the* ***QC*** *key before a cuvette is inserted. If EQC is run while a cuvette is inserted, the message* ***Detector Blocked*** *is displayed and the EQC test fails.*

2. Press **1**. The test chamber warms to temperature and the EQC test begins. The results are displayed while the test is progressing.

3. When the test is completed, the results are displayed on the screen and written to the QC database. Press **CANCEL** to exit the screen.

Note: *Internal EQC will check two levels of QC and the temperature, and it will store each result. If one result fails, the test will stop and record all results as failed. If the user aborts the internal EQC test, the test is not saved to the database or printed.*

QC Using Liquid Quality Control Products:

1. Obtain the liquid quality control products.

   Note*: HEMOCHRON Jr. Quality Controls are recommended. Refer to the package insert for the liquid quality control products for storage and handling information.*

2. Obtain a cuvette for the test to be validated and insert it into the instrument.
3. To run QC when it is not required, press the **QC** key.
4. Select QC NORMAL (or QC ABNORMAL) and enter an Operator ID (optional) for the test.

   Important*: LQC results will be stored in the patient database if QC NORMAL or QC ABNORMAL is not selected for the test.*

5. When **Add Sample** and **Press Start** are displayed, add the appropriate liquid control sample and run the test in the same manner as for a patient sample.

   Note*: If any error messages appear on the instrument screen, remove the cuvette and repeat the test using a new cuvette.*

QC of Cuvettes

Cuvette validation is carried out using the appropriate HEMOCHRON Quality Control product and the test procedure provided.

Acceptable performance ranges for the HEMOCHRON Jr. cuvettes are included with each HEMOCHRON QC product. The cause of out-of-range results is likely attributable to test technique, control material, cuvette and/or the instrument. Refer to the *Troubleshooting* section for additional information.

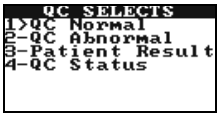
Checking QC Intervals

If EQC tests and/or LQC tests are required to be run at specified intervals, the amount of time remaining before QC must be run on each test can be checked.

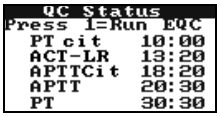
To Check QC Intervals:

***Note**: If a cuvette is **not** inserted in the instrument, pressing QC will immediately display QC Status and will allow the operator to run EQC.*

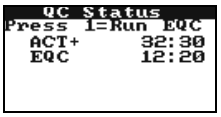
1. With a cuvette inserted, press **QC** to display the QC SELECTS menu:



2. Press **4**. The remaining time (shown as **hours:minutes**) before QC must be run on each test is displayed. Tests are listed in the order which QC will need to be run, with EQC always displayed last:



3. If applicable, the screen will toggle to display the QC time remaining for additional tests.



OPERATING PRECAUTIONS

The AC/DC Power Module should be plugged into a Hospital Grade AC outlet to charge the instrument when it is not in use.

DO NOT open the instrument, as there are no user-serviceable parts and the warranty is violated.

DO NOT remove the AC/DC Power Module from the instrument by pulling on the cord.

DO NOT use cuvettes that are past their marked expiration date or have been improperly stored.

DO NOT use non-ITC cuvettes.

DO NOT force a cuvette into the instrument. If resistance to insertion is encountered, gently remove the cuvette and examine the cuvette slot. Remove any obstruction before attempting further use of the instrument (see *Service and Maintenance* on page 78).

DO NOT use excessive force in pressing the instrument keys.

DO NOT expose the instrument to extreme temperatures (above 37 °C).

DO NOT drop the instrument, and do not use the results if the instrument is dropped during a test.

The use of accessory equipment identified in this manual either in the patient vicinity, or that does not comply with either the equivalent safety requirements of this equipment or IEC 60601-1 or IEC 60601-1-1, may lead to a reduced level of safety in the resulting system.

The HEMOCHRON *Signature Elite* instrument should only be used by healthcare professionals trained and certified in the use of the system and operated in accordance with facility policies and procedures.

All biohazard safety guidelines pertaining to the handling and disposal of human blood should be strictly adhered to when collecting and handing blood specimens and when operating the HEMOCHRON *Signature Elite* Microcoagulation instrument.

Used HEMOCHRON Jr. test cuvettes should be considered as potentially infectious. They should be handled according to individual institutional policies concerning the disposal of potentially infectious materials.

***CAUTION**: Verify that any third-party connectivity software to be used is compatible with the software version of the HEMOCHRON Signature Elite instrument in use. Transferred data will be lost if third-party connectivity software used is not compatible with HEMOCHRON Signature Elite software.*

LIMITATIONS

Test results of the HEMOCHRON *Signature Elite* Microcoagulation instrument are affected by poor technique during blood collection and delivery to the sample well. The accuracy of the test is largely dependent upon the quality of the blood specimen, which is dependent upon the blood sample collection and the transfer of blood to the test cuvette. Refer to the individual assay package insert for specific limitations.

HEMOCHRON *Signature Elite* test results should always be scrutinized in light of a specific patient's condition or anticoagulant therapy. Any test results exhibiting inconsistency with the patient's clinical status should be repeated or supplemented with additional diagnostic tests. Samples with a hematocrit less than 20% or greater than 55% are not recommended, due to an optical density outside the detection level of the HEMOCHRON *Signature Elite* Microcoagulation instrument.

RESULTS MANAGEMENT

Up to 600 patient test results and 600 quality control test results can be stored in the instrument. In addition to test results, the date and time of each test, PID, OID, and user notes are also stored.

***Note**: PID and/or OID are not stored if a value is not entered when the test is run. A PID is not allowed for any QC test.*

***Note**: If an error is encountered with the test or the sample, the error message for the error will be included on the printout. Refer to page 74 for error messages, their cause, and their resolution.*

Printing Results

1. Press **PRINT**/**SCAN** to display the PRINT menu:

Then perform one of the following procedures:

To Print Results of the Last Test:

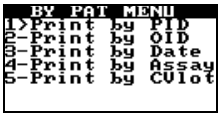
1. Press **1**. Results of the last test are printed.

To Print All Results in a Database:

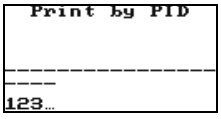
1. Press **2** to print all of the results in the patient database. Or, press **3** to print all of the results in the QC database.

To Print Patient Results:

1. Press **4** to display the menu for printing patient results:



2. Print the results for the desired tests:
   a. To print results for a specific patient, press **1** to display the Print by PID screen:



Scan or type the PID, then press **ENTER**. All test results for the specified patient are printed.

b. To print results obtained by a specific operator, press **2** to display the Print by OID screen.

Scan or type the OID, then press **ENTER**. All patient test results obtained by the specified operator are printed.

c. To print results obtained on a specific date, press **3** to display the Print by Date screen:

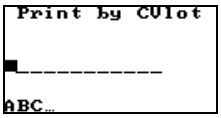
Enter the date using the keypad, then press **ENTER**. All patient test results obtained on the specified date are printed.

d. To print all results for a specific assay, press **4** to display the Print by Assay screen:

***Note**: If the desired assay is not shown, press **7** to display additional assays.*

Enter the number for the assay, then press **ENTER**. All patient test results for the specified assay are printed.

e. To print results for a specific cuvette lot number, press **5** to display the Print by CVlot screen:

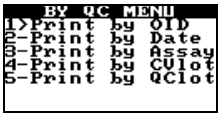


Scan or type the cuvette lot number, then press **ENTER**. All patient test results for the specified cuvette lot number are printed.

f. Press **CANCEL** to return to the menu for printing patient results (Step 1).

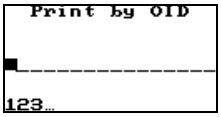
To Print QC Results:

1. Press **5** to display the menu for printing QC results:



2. Print the results for the desired tests:

a. To print QC results obtained by a specific operator, press **1** to display the Print by OID screen:

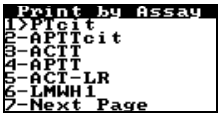


Scan or type the OID, then press **ENTER**. All QC test results obtained by the specified operator are printed.

b. To print results obtained on a specific date, press **2** to display the Print by Date screen:

Enter the date using the keypad, then press **ENTER**. All QC results obtained on the specified date are printed.

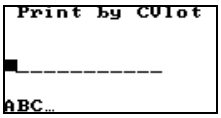
c. To print all results for a specific assay, press **3** to display the Print by Assay screen:



***Note**: If the desired assay is not shown, press **7** to display additional assays.*

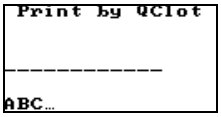
Enter the number for the assay, then press **ENTER**. All QC test results for the specified assay are printed.

d. To print results for a specific cuvette lot number, press **4** to display the Print by CVlot screen:



Scan or type the cuvette lot number, then press **ENTER**. All QC test results for the specified cuvette lot number are printed.

e. To print results for a specific control lot number, press **5** to display the Print by QClot screen:

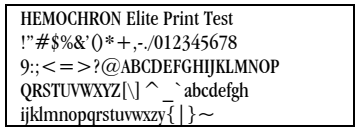


Scan or type the control lot number, then press **ENTER**. All QC test results for the specified control lot number are printed.

f. Press **CANCEL** to return to the menu for printing QC results (Step 1).

To Check Printer Function:

1. Press **6** to output an ASCII character set to an attached printer to verify that the printer port functions properly.



To Abort Printing of Results:

1. Pressing **CANCEL** for three seconds will abort data transmission to the printer. Any data transmitted before **CANCEL** is released will complete printing.

Accessing Print Menu-2

Print Menu-2 allows printing of system information, entering a header, and checking of the printer and barcode scanner.

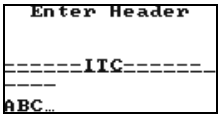
1. Press **PRINT/SCAN** to display the first page of the Print menu:

2. Press **7** to display the second page of the Print menu:

To Enter a Custom Header:

This feature allows creation of a custom header to appear on the top of each printout. The default header is - - -ITC - - -. A custom header can contain up to 20 characters.

1. Display the second page of the Print menu.
2. Press **1** to enter a custom header:



3. Create the custom header using the keypad.

   Press the **NOTE** key to change the data entry mode from alphabetical (ABC; shown above) to numerical (123) or vice versa.

   Note: If alphabetic characters are being entered, advance from the displayed letter to the next letter on that key by pressing the key again before the cursor advances. Release the key (for at least one second) when the selected character is displayed. The character is saved and the cursor advances to the right.

   Use the **CANCEL** key as a left-arrow key and the **ENTER** key as a right-arrow key.

4. When the desired header is displayed, press and hold the **ENTER** key (for at least one second) to save the header. Press and hold the **CANCEL** key to return to the ENTER HEADER prompt without saving the new header.

To Print System Information:

1. Display the second page of the Print menu.
2. Press **2** to print the system software version, system serial number, and program parameters.

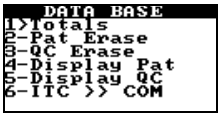
Other Database Operations

Results can be reviewed for both patient and QC tests. The total number of test results that are currently stored can be displayed, the total number of additional test results that can be stored can be displayed, and the results in either the patient database or the quality control database can be erased to make room for additional test results. Finally, POCT-1A communication can be initiated.

***CAUTION**: Results from the oldest test are overwritten if a test is run when the database is full. Therefore, it is important to periodically check, print, archive, and erase database contents.*

To Perform Other Database Operations:

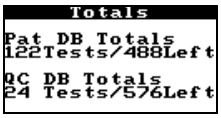
1. Press **DATABASE** to display the Database menu:



Then perform one of the following procedures:

To Display Total Tests and Remaining Tests in the Database:

1. Press **1**. The total number of stored patient records and QC records, plus the number of records that can still be added to the patient database and the QC database are displayed:

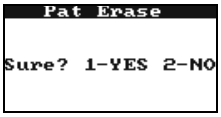


To Delete All Results from a Database:

***Note**: Deleting of results from the database can be disallowed in Configuration Manager. Refer to page 54 for details.*

1. Press **2** to erase the patient database.

   Or, press **3** to erase the QC database.
2. The instrument displays a prompt to confirm deletion of the database:

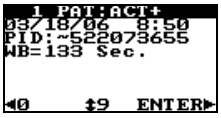


3. Press **1** to confirm deletion. COMPLETED is displayed for two seconds.

   ***Note**: Press **2** or **CANCEL** to cancel erasing of the database.*

To Review Results of the Patient Database:

1. Press **4**. The first page of the results for the most current test record is displayed.

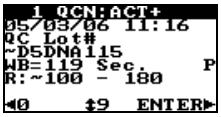


2. Press **9** to display additional pages of the record:

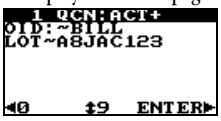
3. To scroll through additional test records, press **ENTER** (for the next record) or **0** (for the previous record).

To Review Results of the QC Database:

1. Press **5**. The first page of the results for the most current test record is displayed.



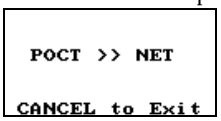
2. Press **9** to display additional pages of the record:



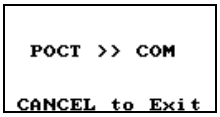
3. To scroll through additional test records, press **ENTER** (for the next record) or **0** (for the previous record).

To Initiate Communication When Using the POCT-1A Communication Protocol:

1. Press **6**. A confirmation is displayed when communication is established:



or



***Note**: Refer to Communication with a PC or Network on page 45 for additional information.*

To Exit Database Operations:

1. Press **CANCEL** to exit.

Downloading QC/Patient Data to Your PC

For information on printing QC/Patient data through your PC using ITC data management software, contact ITC Technical Support.

Acronyms for Error Messages

The following table lists the acronyms for Error Messages when viewing stored Patient or QC records:

Acronym	Description	Display Message
ORH	Out of Range High	Out of Range-Hi
ORL	Out of Range Low	Out of Range-Lo
SNS	Sample Not Seen	Sample Not Seen
STS	Sample Too Small	Sample Too Small
STL	Sample Too Large	Sample Too Large
TTO	Temp Timeout	Heater Too Cool
TTH	Temp Too High	Heater Too Hot
SPF	Sample Position Fault	Sample Pos Fault
UAT	User Aborted Test	User Abort
BAT	Battery Fault	Battery Fault
PMS	Premature Sample	Premature Sample
DEF	Detector Fault	Detector Fault
BTH	Battery Too High	Battery Too High
XTH	External Power Too High	External Too High
RTC	Real Time Clock Fault	RTC Fault

COMMUNICATION WITH A PC OR NETWORK

The instrument can communicate directly with a personal computer (using the COM port) or a network (using the Ethernet port). One of two communication protocols can be selected:

- An ITC proprietary communication protocol that allows records to be transferred from the instrument and allows the instrument to be configured using ITC software such as HEMOCHRON *Configuration Manager*.
- A communication protocol that meets CLSI POCT-1A standards. This protocol allows the instrument to communicate with any software or device that is compliant with POCT-1A.

Communicating When the POCT-1A Communication Protocol is Used

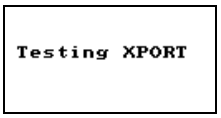
When the CLSI POCT-1A compliant communication protocol is used, communication must be initiated from the instrument.

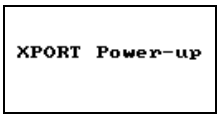
1. If necessary, check the instrument Communications menu and verify that the POCT-1A communication protocol and the desired communication port (NET or COM) are specified:

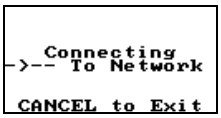
or

***Note**: The Communications menu is accessed from the Supervisor menu (page 20).*

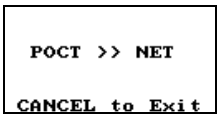
2. From either the Database menu or the Communications menu, select **6–POCT >> NET** (or **6–POCT >> COM**, if the COM port is being used) to initiate communication:

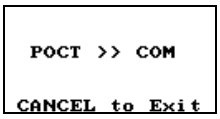


and


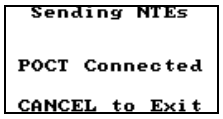
and


3. A confirmation is displayed when communication is established:

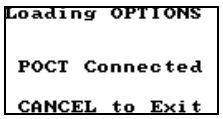


or


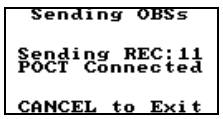
4. At the software application (for example, HEMOCHRON *Configuration Manager* on the personal computer), start data transfer. Progress of data transfer is displayed as data transfer proceeds:



Example: *Reading the configuration from an instrument using HEMOCHRON Configuration Manager software.*



Example: *Writing a new configuration to an instrument using HEMOCHRON Configuration Manager software.*



Example: *Exporting test records from an instrument using HEMOCHRON ReportMaker software.*

5. The message **Disconnecting Network** is displayed upon completion of data transfer, and the instrument main menu is then displayed.

Communicating When the ITC Proprietary Communication Protocol is Used

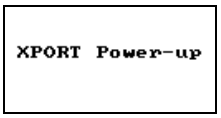
When the ITC proprietary communication protocol is used, communication must be initiated from the personal computer or network.

1. If necessary, check the instrument Communications menu and verify that the ITC proprietary communication protocol and the desired communication port (NET or COM) are specified:

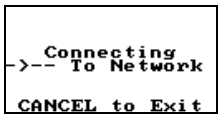
or

***Note**: The Communications menu is accessed from the Supervisor menu (page 20).*

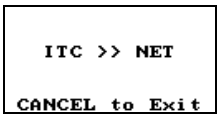
2. At the software application (for example, HEMOCHRON *Configuration Manager* on the personal computer), start data transfer. Status messages may be displayed on the instrument during initiation of communication,



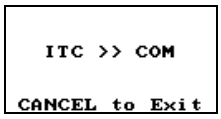
and



and confirmation is displayed when communication is established:



or

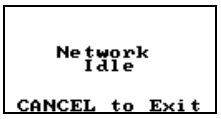


3. Initiate data transfer at the software application. Confirmation of data transfer is displayed as data transfer proceeds:

4. The message **Shutting Down** is displayed upon completion of data transfer, and the instrument then shuts down.

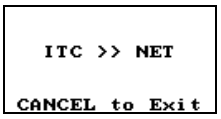
Notification of Idle Network

A message on the instrument alerts the operator if the network is idle for more than five seconds during a communication session:



Cancelling a Communication Session

A communication session can be cancelled by pressing the CANCEL key on the instrument. This can be done whenever the CANCEL prompt is displayed on the instrument:



CONFIGURATION MANAGER

HEMOCHRON *Configuration Manager* (HCM) software V3.0 or higher allows the supervisor to configure HEMOCHRON *Signature Elite* instruments so they meet the needs of the laboratory.

The configuration is performed on a personal computer with installed HEMOCHRON *Configuration Manager* software. The computer is connected to the instrument by means of a COM port or a network connection. The personal computer must meet the following minimum requirements:

- Pentium II 400 MHz or higher microprocessor
- Hard disk with at least 50 MB of free space
- At least 128 megabytes (MB) of random-access memory (RAM)
- Microsoft Windows NT, 2000, or XP (if you are running Windows 2000 or XP, you must have System Administrator security privileges to install the software)
- VGA 800x600 or higher resolution supported by Microsoft Windows.
- At least one available RS-232 serial port (if an instrument is connected directly to the personal computer by means of a COM port)
- A network connection (if an instrument is connected to the personal computer by means of a network)
- CD-ROM drive

Installing *Configuration Manager* Software

The Setup program creates HEMOCHRON *Configuration Manager* working directories. It copies programs and configuration files to the working directories and adds the HEMOCHRON *Configuration Manager* (ITC CM) program icon to the desktop.

1. Start Microsoft Windows.
2. Insert the HEMOCHRON *Configuration Manager* installation CD-ROM in the CD drive.
3. Follow the instructions on the screen.

   ***Note**: You will be prompted to specify a folder for the installation.*
4. A message will be displayed when the software is successfully loaded. After the message is displayed, remove the CD from the computer.
5. Shut down and restart the computer if prompted to do so.

Connecting an Instrument

The HEMOCHRON *Signature Elite* instrument that is being configured must be connected to HEMOCHRON *Configuration Manager*. This can be done using either the COM port or a network connection.

1. Connect the HEMOCHRON *Signature Elite* instrument to the personal computer on which HEMOCHRON *Configuration Manager* is installed, using either the computer interface cable included with the instrument or a network interface cable.

   ***Note**: If the computer interface cable is used, connect one end of the cable to the computer port on the side of the instrument and the other end to an unused COM port on the personal computer. If a network interface cable is used, connect one end of the cable to the Ethernet port on the side of the HEMOCHRON Signature Elite instrument and the other end to a network connection port. Refer to page 23 for connection details.*

   ***Note**: A computer interface cable is included with the instrument and CD, or a separate PCKIT (Personal Computer Interface Cable) can be obtained from ITC. Alternatively, the cable can be prepared as outlined on page 24.*

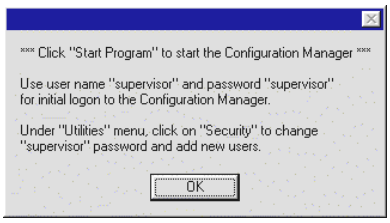
   ***Note**: It is recommended that the instrument is on external power while it is connected to the personal computer.*
2. Check the instrument Communications menu and verify that the desired communication protocol and communication port (NET or COM) are specified (page 20).

   ***Note:** When the POCT-1A communication protocol is used, HEMOCHRON Configuration Manager cannot communicate with the instrument over the COM port.*
3. Follow instructions on page 45 for establishing communication.

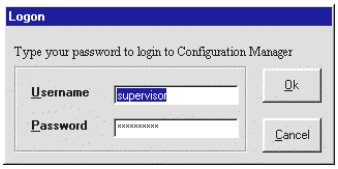
Starting *Configuration Manager*

1. Select the ITC **CM** program icon. The Startup window is displayed:

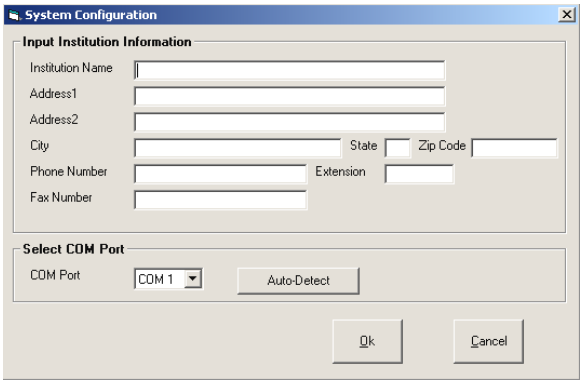
2. When HEMOCHRON *Configuration Manager* software is run for the first time, instructions are displayed to logon using the default user name and password:


*** Click "Start Program" to start the Configuration Manager ***
Use user name "supervisor" and password "supervisor" for initial logon to the Configuration Manager.
Under "Utilities" menu, click on "Security" to change "supervisor" password and add new users.
OK

   a. Click **OK** and then click **Start Program**. The Logon dialog box is displayed with the default user name (supervisor) and password (supervisor):



   b. Click **OK**. The System Configuration dialog box is displayed:

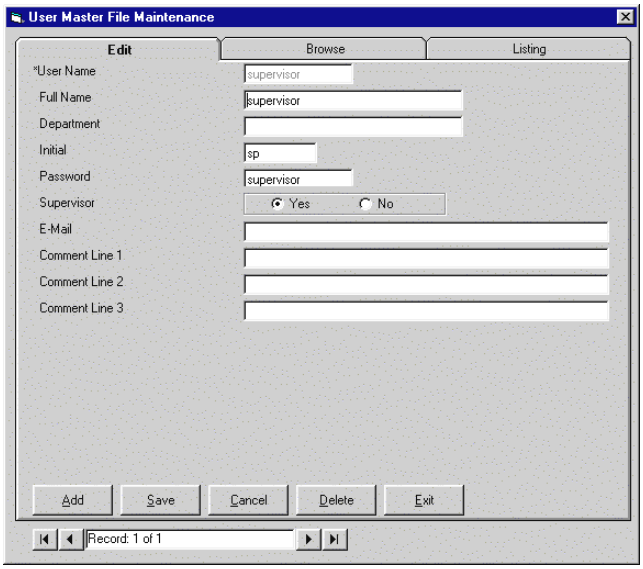


c. Enter the institution name, address, and/or contact information.

Click **Auto-Detect** to automatically detect the PC COM port that is being used when connected to *Signature Elite*. Alternately, click the drop-down arrow in the COM Port box and select the number of the COM port used.

***Note**: To modify these settings at a later date, select **System Configuration** from the Utilities menu.*

d. Click **OK**. The information is saved, and the User Master File Maintenance dialog box is displayed:



e. To change the default "Supervisor" user password, enter a new password. Ensure that the **Yes** button is selected for Supervisor access, then click **Save**,

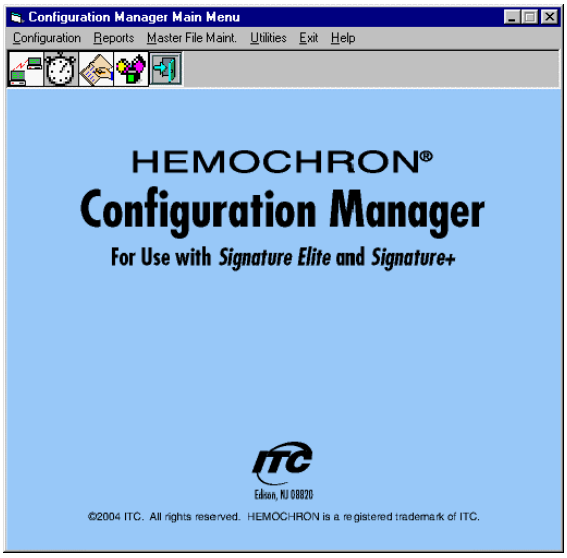
***Note**: The "Supervisor" user name cannot be deleted. However, the default user password should be changed as shown above. All commands are accessible to anyone until then.*

3. Thereafter, click **Start Program** to display the Logon dialog box:

4. Enter your user name and password, then click **OK**.

Menus

Menus for HEMOCHRON *Configuration Manager* functions are displayed at the top of the main window:


Configuration Manager Main Menu
Configuration Reports Master File Maint. Utilities Exit Help
HEMOCHRON®
Configuration Manager
For Use with Signature Elite and Signature+
Edison, NJ 08820
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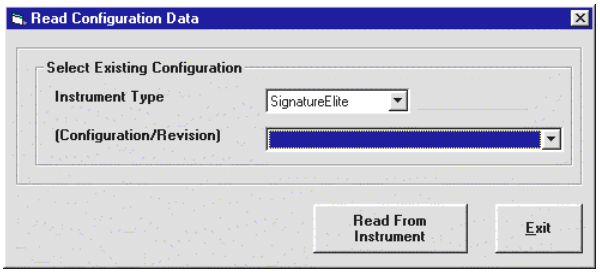
The use of each menu is described below:

Menu	Purpose
Configuration	Display the Read Configuration Data dialog box. This dialog box allows the operator to set the various configuration options (see page 53).
Reports	Display and print listings of configuration parameters, instruments, operators (see page 67), and audit trail.
Master File Maintenance	Display, modify, add, and delete instrument information.
Utilities	Rebuild and compress the database. Purge selected records. Set up system time check. Display, modify, add, and delete operator information. Convert HEMOCHRON *Configuration Manager* software V1.0 or V2.0 data to V3.0.
Exit	Log off and/or exit the system.
Help	Display the version number of HEMOCHRON *Configuration Manager* software that is installed. Access **Help**.

Reading or Loading Configuration Data

Select **Configuration** in the *Configuration Manager* main menu to display the Read Configuration Data dialog box. This dialog box allows configuration data to be read from a connected instrument or a different configuration file to be loaded:



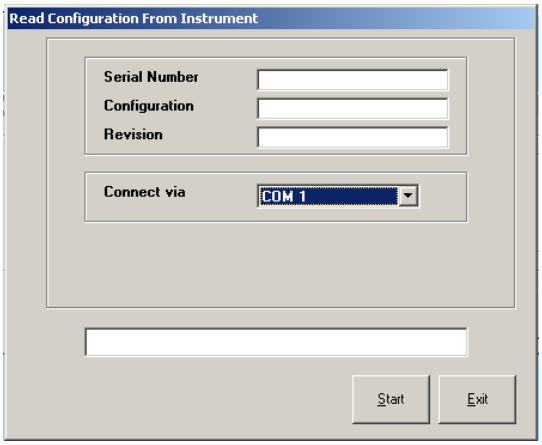
***Note**: HEMOCHRON Configuration Manager uses a Microsoft Windows user interface. Software features are intuitive and easy to learn. Refer to Windows documentation for instructions on navigation, access to commands and Help, execution of commands, and shortcuts that can be taken.*

***Note**: The Instrument Type drop-down list is used when loading a configuration from the database. If a configuration is read from a connected instrument, the instrument type is automatically detected and displayed.*

***Note**: Load the default HEMOCHRON Signature Elite settings by selecting **Factory Default** from the Configuration/Revision drop-down list. These settings can be modified and saved under a different configuration file name. The Factory Default configuration file cannot be overwritten or purged from the database.*

To Read Configuration Data from a Connected Instrument:

1. Click **Read From Instrument**. The Read Configuration from Instrument dialog box is displayed:

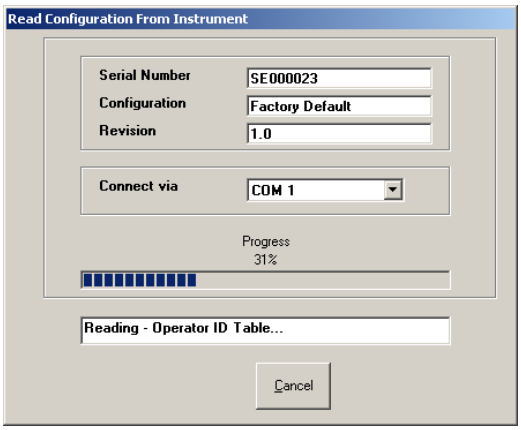


2. Establish communication to the instrument as described on pages 45 and 46.

   ***Note**: If the instrument is connected over a network, select **<Listen on Network>** from the drop-down list in the Connect via box. Otherwise, if prompted, designate the COM port by selecting it from the drop-down list.*

   ***Note:** When the POCT-1A communication protocol is used, HEMOCHRON Configuration Manager cannot communicate with the instrument over the COM port.*

3. Click **Start**. Configuration data are read from the connected instrument:



***Note**: The instrument serial number and the name and revision level of the instrument configuration file are displayed in the Read Configuration dialog box. Progress of reading of configuration data is displayed in the status lines.*

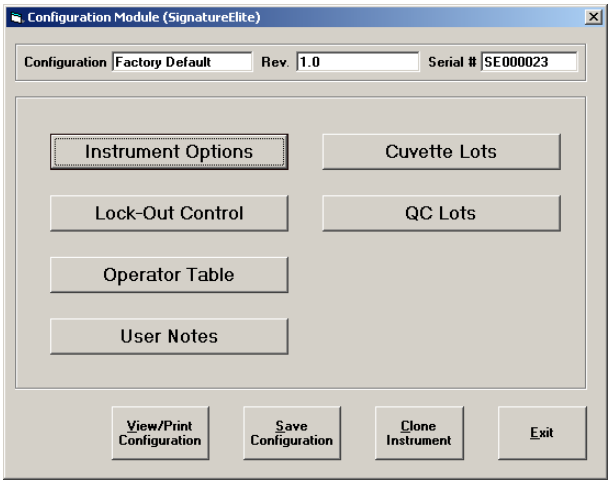
***Note**: If the ITC proprietary communication protocol is used, **Transferring Data** is displayed on the connected HEMOCHRON Signature Elite instrument during data transfer. If the connection is not made, an error message is displayed on the personal computer. Select **Retry** on the error message box to make the connection.*

***Note**: If the POCT-1A communication protocol is used, specific messages indicate the progress of data transfer. If the connection is not made, the instrument will beep, display **Network Timed Out!**, and prompt that the instrument is ready to accept a cuvette.*

4. When reading of configuration data is successfully completed, a confirmation dialog box is displayed. Click **OK** to display the Configuration Module dialog box (see below).

To Load a Configuration File from the Database:

1. Select the instrument type from the *Instrument Type* drop-down list.
2. Select the file from the *Select Existing Configuration* drop-down list.
3. Click **Yes** to the prompt for loading the selected file.
4. Click **OK** when reading of the configuration data is complete. The Configuration Module dialog box is displayed:



Setting Configuration Options

Reading a configuration file from an instrument or loading a configuration file from the database will open the Configuration Module dialog box (page 52). Buttons on the dialog box allow the supervisor to display and/or modify the instrument configuration:

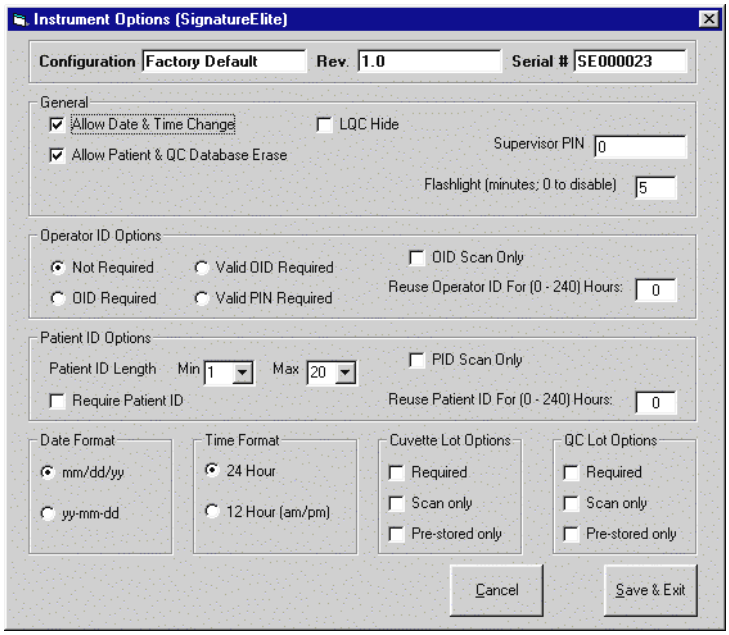
Button	Purpose
Instrument Options **a. General Options**	1. Specify when the display panel is illuminated. 2. Allow operators to change the date or time. 3. Allow operators to erase a database. 4. Suppress display of QC results. 5. Enter instrument supervisor PIN.
b. Operator ID Options	1. Require entry of an Operator ID (OID) before a test can be run. 2. Require that the supervisor-specified OID or Personal Identification Number (PIN) must be entered by an operator in order to operate the instrument. 3. Specify that the OID for the previous test is automatically entered for a specified length of time or until a new OID is entered. 4. Specify that the barcode scanner must be used for entering the Operator ID.
c. Patient ID Options	1. Specify the number of digits for a Patient ID (PID). 2. Require entry of a (PID) before a test can be run. 3. Specify that the PID for the previous test is automatically entered for a specified length of time or until a new PID is entered. 4. Specify that the barcode scanner must be used for entering the Patient ID.
d. Date Format Options	1. Specify a date format of **MM/DD/YY** or **YY-MM-DD**.
e. Time Format Options	1. Specify a **24-hour** or **12-hour** (am and pm) time format.
f. Cuvette Lot Options/ QC Lot Options	1. Require entry of a cuvette lot number and/or QC lot number. 2. Specify that the barcode scanner must be used for entering the cuvette lot number and/or QC lot number. 3. Require that cuvette and/or QC lot numbers that are used can only be selected from a list specified by the supervisor.
Lock-Out Control **a. QC Lockout**	1. Specify whether electronic quality control (EQC) testing must be run after a specified time interval has elapsed. 2. Specify either 300 seconds or 500 seconds for the EQC level 2 test. 3. Specify automatic running of EQC tests at scheduled intervals. 4. For each test type, specify whether normal and/or abnormal liquid quality control (LQC) testing must be run after a specified time interval has elapsed. 5. Prohibit specific test(s) from being performed on the instrument. 6. If EQC and/or LQC testing must be run after a specified interval, specify the number of additional tests that can be run per assay (the 911 exceptions) after the time interval has elapsed.
b. QC Exceptions	1. Specify the number of EQC or LQC test failures that are allowed before the instrument is locked and must be reset by the supervisor.

Button	Purpose
Operator Table	1. Specify an OID, PIN, and/or certification expiration date for an operator.
User Notes	1. Specify user-selectable notes that can be entered at the time of a test.
Cuvette Lots	1. Specify up to five cuvette lot numbers and expiration dates that are to be used for each assay.
QC Lots	1. Specify up five lot numbers, expiration dates, and expected ranges for level 1 (normal) and level 2 (abnormal) controls for each assay.

Specifying Instrument Options

Instrument options specify how the instrument communicates with the operator.

1. Click **Instrument Options** on the Configuration Module dialog box (page 52) to display the Instrument Options dialog box. Information concerning the configuration file is displayed:



Instrument General Options

1. **Allow Date & Time Change**: Enter a check mark to allow the operator to change the date and time on the instrument.
2. **Allow Patient & QC Database Erase**: Enter a check mark to allow an operator to erase the patient database or the QC database.
3. **LQC Hide**: Enter a check mark to specify that **Pass** or **Fail** is displayed in place of numerical QC Results.
4. **Supervisor PIN**: Enter an optional PIN number (from 1 to 9 digits) to control access to the Supervisor menu in the HEMOCHRON *Signature Elite* instrument.
5. **Flashlight**: Enter the number of minutes that the display will be illuminated after a cuvette is inserted and after results are displayed. Valid range for screen illumination is from **0** to **100** minutes.

   Note: *If **0** is entered, the display is illuminated at all times.*

Operator ID Options

1. **Not Required**: Select if entry of an Operator ID (OID) or PIN is not required when running a test.
2. **OID Required**: Select to require entry of an OID (any OID) when running a test.
3. **Valid OID Required:** Select to require entry of an OID that is included in the Operator Table and is within the expiration period (if an expiration date is enabled for that user).
4. **Valid PIN Required:** Select to require entry of an authorized Operator PIN. All PIN numbers must have a corresponding Operator ID in the Operator Table.

   Note: *Only one of the alternatives listed in steps **1** through **4** can be selected. Authorized OIDs and/or PINs are entered in the Operator Table. Both OID and PIN should be unique for each authorized operator or group in the Operator Table (see page 61).*

5. **OID Scan Only:** Enter a check mark to specify that the OID must be scanned.

   Note: *If **OID Scan Only** is enabled, the operator is prompted to scan the OID when running a test. The operator can still enter the OID manually by pressing the **ID** key (as indicated by the **ID=Manual Entry** prompt), but the OID must be entered twice.*

6. **Reuse Operator ID**: Enter a value (from **1** to **240** hours) to allow the instrument to use the OID from the previous test as the default entry for the current test. The OID will be entered by default for the specified length of time and will be flagged as a manual entry in the database.

   Note: *If **0** is entered, the OID will not be reused. The default OID can be changed if needed.*

Patient ID Options

1. **Require Patient ID**: Enter a check mark to require entry of a PID when running a patient test.
2. **Patient ID Length**: Select the minimum **(**from **1** to **20)** and maximum **(**from **1** to **20)** number of digits that must be entered for a patient ID.
3. **PID Scan Only:** Enter a check mark to specify that the PID must be scanned.

   Note: *If **PID Scan Only** is enabled, the operator is prompted to scan the PID when running a test. The operator can still enter the PID manually by pressing the **ID** key (as indicated by the **ID=Manual Entry** prompt), but the PID must be entered twice.*

4. **Reuse Patient ID**: Enter a value (from **1** to **240** hours) to allow the instrument to use the PID from the previous test as the default entry for the current test. The PID will be entered by default for the specified length of time and will be flagged as a manual entry in the database.

   Note: *If **0** is entered, the PID will not be reused. The default PID can be changed by entering a new PID.*

Date Format

1. **Date Format**: Select **MM/DD/YY** to display June 1, 2006 as 06/01/06. Select **YY-MM-DD** to display June 1, 2006 as **06-06-01**.

Time Format

1. **Time Format**: Select **24 Hour** to display 7:15 pm as 19:15. Select **12 Hour** to display 7:15 pm as 7:15 pm.

Cuvette Lot Options

1. **Required**: Enter a check mark to require entry of a cuvette lot number and expiration date when running a test.
2. **Scan only**: Enter a check mark to specify the cuvette information can only be entered using the barcode scanner.

   Note: *If **Scan Only** is enabled, the operator is prompted to scan the cuvette information when running a test. The operator can still enter the information manually by pressing the **7** key (as indicated by the **7=Manual Entry** prompt), but the information must be entered twice. Refer to page 28 for additional information.*

3. **Pre-stored only**: Enter a check mark to specify the cuvette information can only be selected from a list of lot numbers specified by the supervisor.

   Note: *Up to five cuvette lot numbers and expiration dates can be specified for each assay (see page 63).*

   Note*: If more than five cuvette lot numbers per assay are scanned or entered, the lot number(s) with the closest expiration date will be deleted.*

QC Lot Options

1. **Required**: Enter a check mark to require entry of a QC lot number when running a quality control test.
2. **Scan only**: Enter a check mark to specify the QC lot number can only be entered using the barcode scanner.

   Note: *If* ***Scan only*** *is enabled, the operator is prompted to scan the QC information when running a test. The operator can still enter the QC information manually by pressing the* **7** *key (as indicated by the* **7=*Manual Entry*** *prompt), but the QC information must be entered twice. Refer to page 32 for additional information.*
3. **Pre-stored only**: Enter a check mark to specify the QC lot number can only be selected from a stored list.

   Note: *Up to five QC lot numbers, expiration dates, and ranges can be specified for each assay for both level 1 and level 2 controls (see page 64).*

   Note*: If more than five QC lot numbers per assay are scanned or entered for level 1 and/or level 2 controls, the lot number(s) with the closest expiration date will be deleted.*

Saving the Options

1. Click **Save & Exit** to save the specified options and cancel display of the dialog box.
   Note*:* ***Cancel*** *clears all fields without saving any parameters.*

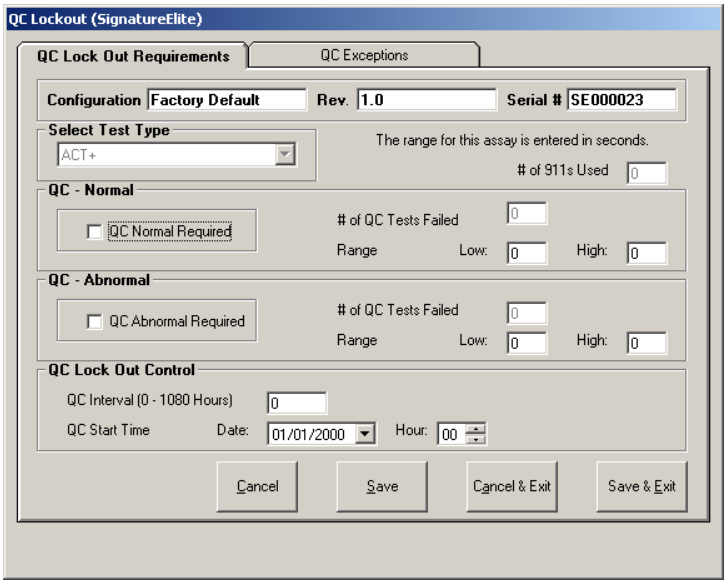
Specifying QC Lockout Parameters

QC lockout parameters specify the maximum length of time that can elapse before liquid quality control (LQC) or electronic quality control (EQC) must be successfully run (**QC Interval**). When the lockout interval has elapsed and the test cuvette is inserted into the instrument, the user will be prompted to perform the appropriate QC.

If 911 Limits are enabled, the user will be offered the choice to run a patient test. If this option is selected, the instrument displays the number (from **0** to **240**) of remaining tests per assay that can be run (the 911 override) before QC must be performed (see *To Specify QC Exceptions* on page 59). Separate requirements can be specified for the frequency at which EQC and LQC for various tests must be run at normal and abnormal levels.

To Specify Lockout Parameters for All Tests Except EQC:

1. Click **Lock-Out Control** on the Configuration Module dialog box (page 52) to display the QC Lockout dialog box. Select the QC Lock Out Requirements tab (if needed).
2. Select the test for specifying lockout parameters. Current settings for the test are displayed:



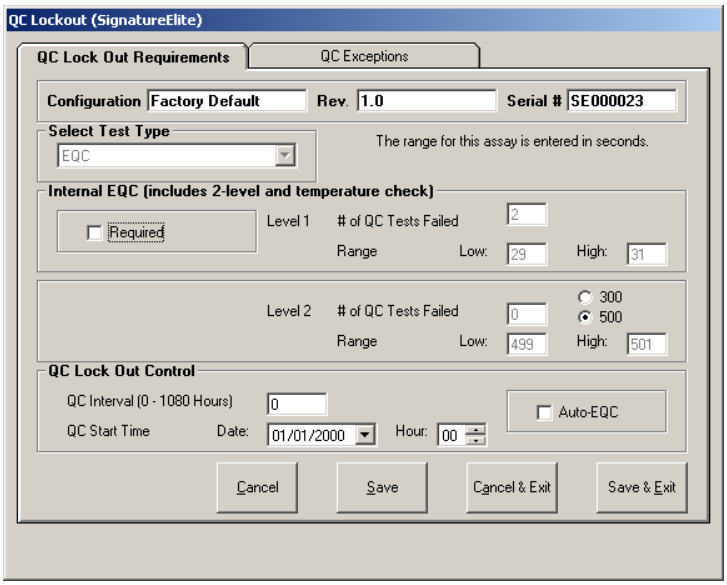
***Note**: The number of patient tests that have already been run against the 911 override limit is displayed in the # of 911s Used field when a configuration is read from an instrument. This value is automatically reset to zero when QC is successfully run.*

3. Enter a check mark in the **QC Normal Required** box to require QC Normal testing to be run at a specified interval.
   ***Note**: The number of QC Normal tests that have been run and failed is displayed in the #of QC Tests Failed field.*
4. (If QC Lot Options are not specified) Designate the acceptable range for Normal LQC of the specified test by entering a value in the **Low** and **High** fields.
   ***Note**: If **Required**, **Scan only**, and/or **Pre-stored only** is specified for QC Lot Options, the **Low** and **High** fields are not displayed.*
5. Enter a check mark in the **QC Abnormal Required** box to require QC Abnormal testing to be run at a specified interval.
   ***Note**: The number of QC Abnormal tests that have been run and failed is displayed in the #of QC Tests Failed field.*

6. (If QC Lot Options are not specified) Designate the acceptable range for Abnormal LQC of the specified test by entering a value in the **Low** and **High** fields.
   ***Note**: If **Required**, **Scan only**, and/or **Pre-stored only** is specified for QC Lot Options, the **Low** and **High** fields are not displayed.*
7. (If the QC testing displayed on the tab is required) Enter the maximum length of time (the QC Interval, from 0 to 1080 hours) that can elapse before the QC testing must be successfully run.
   ***Note**: The interval time resets upon successful completion of QC.*
8. (If the QC testing displayed on the tab is required) Enter the date and time when the required QC testing displayed on the tab must be run for the first time. If a start date and time are not entered, the QC testing will be required immediately after Configuration is downloaded to an instrument.
   ***Note**: Subsequent dates and times will be determined automatically from the QC interval.*
9. Repeat steps **2** through **6** as needed for additional QC testing.
10. Click **Save** to save the QC lockout parameters for each test type individually.
    ***Note**: Click **Cancel** to clear the fields without saving the modified parameters. **Save & Exit** saves the EQC/LQC lockout parameters and closes the dialog box.*
11. To disable a particular assay from being run, enter a check mark in the **QC Normal** (or **Abnormal**) **Required** box, enter a range, and then enter **0** for the QC Interval. The message DISALLOWED ASSAY … REMOVE CUVETTE displays when a cuvette for that test is inserted.

To Specify Lockout Parameters for EQC:

1. Click **Lock-Out Control** on the Configuration Module dialog box (page 52) to display the QC Lockout dialog box. Select the QC Lock Out Requirements tab (if needed), and then select EQC:



2. Enter a check mark in the **Required** box to specify that EQC testing is to be run at a specified interval.
   ***Note**: The number of EQC tests that have been run and failed is displayed in the #of QC Tests Failed fields. The expected range for each level is displayed in the Low and High fields.*
3. Select either **300** seconds or **500** seconds for the level 2 EQC test.
4. (If EQC testing is required) Enter the maximum length of time (the QC Interval, from **1** to **1080** hours) that can elapse before EQC testing must be successfully run.
   ***Note**: The interval time resets upon successful completion of EQC.*

5. (If EQC testing is required) Enter the date and time when EQC testing must be run for the first time. If a start date and time are not entered, EQC testing will be required immediately after the configuration is downloaded to an instrument.

   ***Note**: Subsequent dates and times will be determined automatically from the QC interval.*

6. **Auto EQC**: Enter a check mark to specify that EQC should be automatically run at the specified interval.

   ***Note**: It Auto EQC is selected and the HEMOCHRON Signature Elite is connected to a power adapter, the instrument will remain on and perform the required EQC test at the appropriate interval. The results will be automatically stored in the database.*

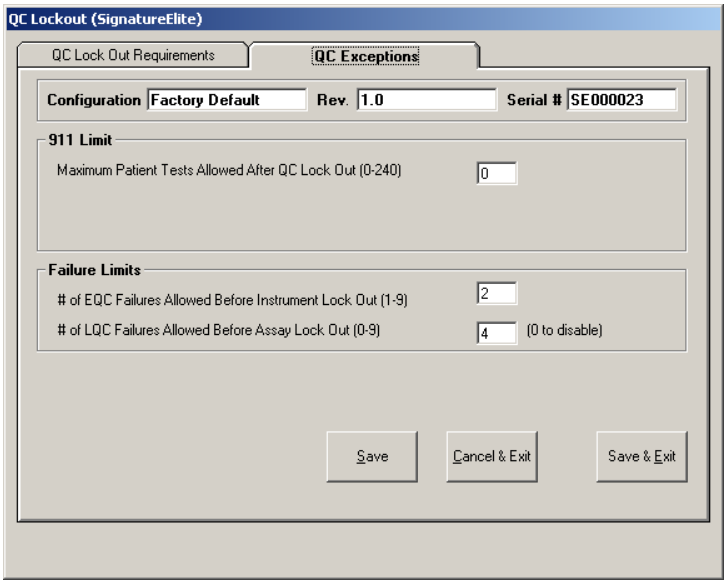
   ***Important**: It Auto EQC is selected, ensure that cuvettes are routinely removed from the instrument after completing a test. If EQC is run while a cuvette is inserted, the message **Detector Blocked** is displayed and the EQC test fails.*

7. Click **Save** to save the EQC lockout parameters.

   ***Note**: Click **Cancel** to clear the fields without saving the modified parameters. **Save & Exit** saves the EQC lockout parameters and closes the dialog box.*

To Specify QC Exceptions:

1. Click **Lock-Out Control** on the Configuration Module dialog box (page 52) to display the QC Lockout dialog box.
2. Select the QC Exceptions tab:



***Note**: Entries made on the QC Exceptions tab apply to all assays.*

911 Limit

1. Enter the maximum number of patient tests (the 911 Limit, from **0** to **240** tests) that can be run after the specified EQC/LQC lockout interval has been reached an assay. When the 911 limit is reached for an assay, that assay cannot be run until a successful QC test is run for that assay or until the instrument is unlocked (see page 60) using *Configuration Manager*.

   ***Note**: The number of patient tests that have already been run against the current 911 limit is displayed when read from an instrument.*

Failure Limit

1. EQC Failure Limit: Enter the maximum number of times that a failed EQC test can be rerun before the system will lock (from **1** to **9** tests).
2. LQC Failure Limit: Enter the maximum number of times that a failed LQC test can be rerun before the system will lock (from **1** to **9** tests).

***Note**: Setting the failure limit to **0** (zero) disables lockout by failure count.*

Saving the Options

1. Click **Save** to save the QC Exceptions parameters.

***Note**: **Cancel** clears all fields without saving any parameters. **Save & Exit** saves the EQC/LQC lockout parameters and closes the dialog box.*

To Unlock an Instrument that has Reached QC Failure Limit or the 911 Limit

***Note**: The HEMOCHRON Signature Elite must be connected to the Configuration Manager and the instrument configuration information read by clicking on **Read Configuration from Instrument**.*

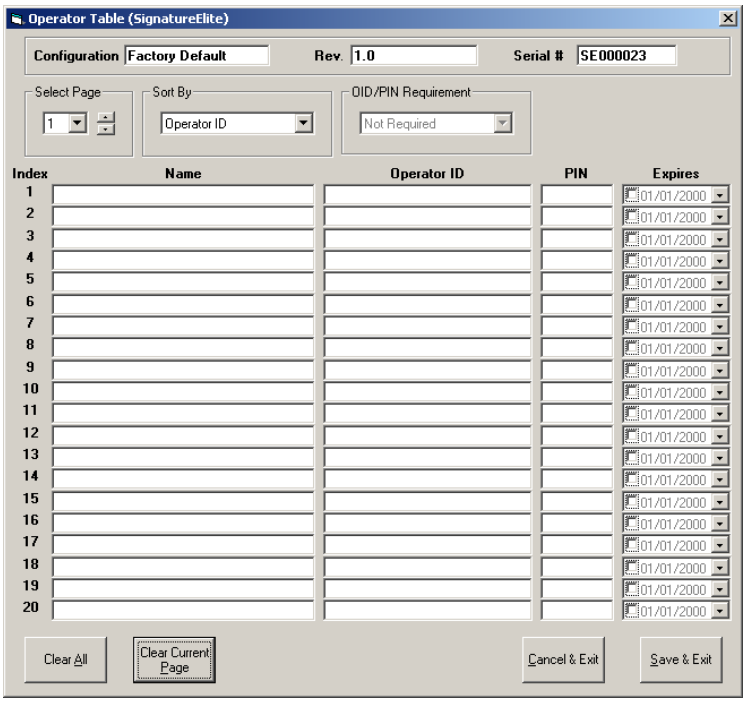
1. After the configuration data from the instrument has been read, select **Clone Instrument**. The Clear Instrument Counts dialog box is displayed (see page 66).
2. Place check marks in both check boxes to reset the failure counts and 911 use counts on cloning.
3. Click **OK**. The Write Configuration dialog box is displayed (page 66).
4. Click **Start**. The reset configuration is written to the instrument.

***Note**: A message box is displayed when writing of the configuration data is complete. Click **OK** to acknowledge the message. Then click **Exit** to cancel display of the Configuration Module dialog box.*

Specifying Operator IDs and/or Personal Identification Numbers

The Operator Table allows the supervisor to enter a name for each operator and then specify an Operator ID (OID), Personal Identification Number (PIN), and/or certification expiration date for each operator (or a group of operators). The supervisor can then specify in the *Instrument Options* dialog box (see page 54) whether entry of an OID or PIN that is included on the Operator Table is required before the instrument can be operated.

1. Click **Operator Table** on the Configuration Module dialog box (page 52) to display the Operator Table dialog box:



2. (Optional) Enter the name of each operator.
   ***Note**: The operator's name is for reference only. It is not stored in the instrument.*
3. Enter or scan an Operator ID (up to 16 alphanumeric characters) for each operator.

   ***Note**: OIDs may be scanned using the barcode scanner through the Supervisor menu and uploaded to Configuration Manager.*

   ***Note**: If OIDs will be entered using the instrument keypad, OIDs should contain only those letters, numerals, and/or characters that can be entered using the **0** through **9** keys on the keypad.*

   ***Note**: An OID that is not included in the Operator Table will not be allowed to run a test if **Valid OID Required** is selected in the Instrument Options dialog box (see page 54). If **OID Required** is selected, any OID can be entered when running a test.*
4. (Optional) Enter a numeric PIN (up to 9 digits) for each operator. The PIN can be any number other than zero (**0**).
   ***Note**: A unique PIN can be assigned for each authorized operator, or a single OID and PIN can be used to allow operation by any operator that enters the correct code.*

5. (Optional) Specify an expiration date for certification of an operator by entering a check mark in the *Expires* box for that operator and then selecting the expiration date from the pop-up calendar.

   ***Note**: An operator with expired certification will not be allowed to run a test if **Valid OID Required** is selected in the Instrument Options dialog box (see page 54). If **OID Required** is selected, any OID can be entered when running a test.*

6. To view OIDs without a PIN or expiration date, select the drop-down arrow in the *Sort By* box and select **PIN** or **Expiration Date** to sort the OIDs in order of their PIN or expiration date. This places OIDs without a PIN or expiration date at the beginning of the table.

   ***Important**: Sorting OIDs by expiration date places those OIDs with the expiration field unchecked and grayed at the beginning of the list. However, the dates that are displayed in the grayed fields are not refreshed and are incorrect. Expiration dates that are displayed for OIDs with enabled (checked) expiration dates are correct.*

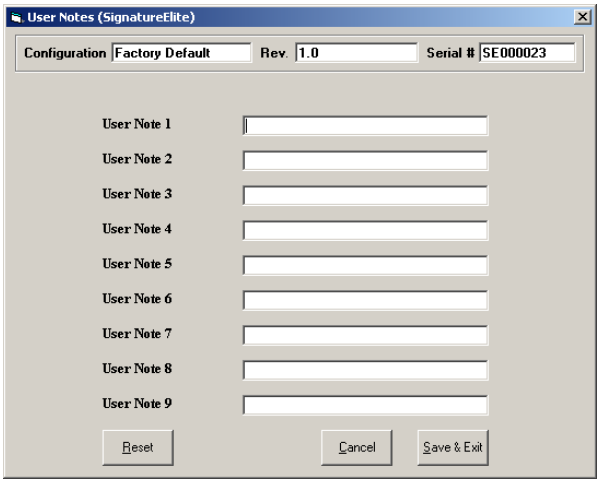
7. The *OID/PIN Requirement* box displays the OID/PIN requirements that are currently set under Instrument Options (see page 54). These options are all mutually exclusive.

8. Click **Save & Exit** to save changes to the Operator Table and exit the dialog box.
   ***Note: Cancel** removes the dialog box without saving changes. **Clear Current Page** clears all information from the current page of the Operator Table. **Clear All** clears all information from the entire Operator Table.*

Specifying User Notes

Up to nine customized notes can be entered into the **User Notes** menu of an instrument. Up to two of these notes can be selected and appended to a test record by the operator when the test is run.

1. Click **User Notes** on the Configuration Module dialog box (page 52) to display the User Notes dialog box. Each field label includes the instrument numeral key that will enter that note when the **User Notes** menu is displayed on the instrument (page 33):



2. Enter a note (up to 16 characters) for each key.

   ***Note: No note** is displayed on the HEMOCHRON Signature Elite instrument if a note is not entered for that note number.*

3. Click **Save & Exit** to save the specified notes and exit the dialog box.

   ***Note: Reset** clears all fields. **Cancel** cancels display of the dialog box without saving the modified notes.*

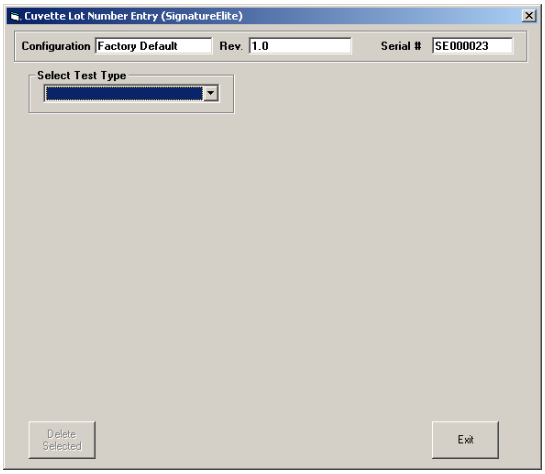
Entering Cuvette Lot Numbers and Expiration Dates

Up to five cuvette lot numbers and expiration dates can be entered for each assay type. Selection or scanning of a cuvette lot number is only allowed when **Required**, **Scan only**, and/or **Pre-stored only** is specified for *Cuvette Lot Options* (see page 55).

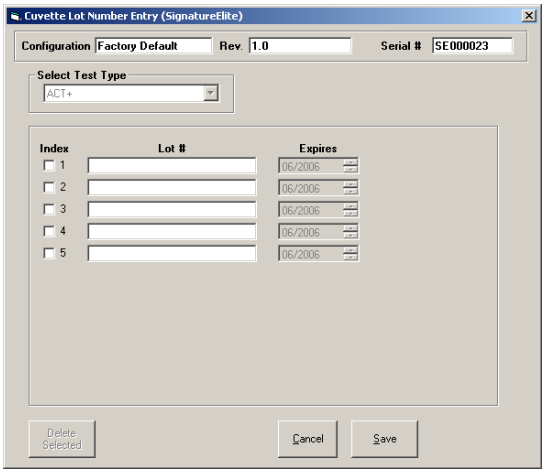
***Note**: Cuvette lot numbers may be scanned using the barcode scanner through the Supervisor menu and uploaded to Configuration Manager (page 18).*

***Note**: Cuvette lot numbers that are manually entered into the HEMOCHRON Signature Elite instrument when running a test are only saved to that particular test record and are not uploaded to Configuration Manager.*

1. Click **Cuvette Lots** on the Configuration Module dialog box (page 52) to display the Cuvette Lot Number Entry dialog box:



2. Select an assay from the **Select Test Type** drop-down list to display the form for entering cuvette lot numbers for that assay and their expiration dates:



3. Enter the lot number and expiration date for up to five cuvette lots.
4. Click **Save** to save the cuvette lot information for the specified assay.

***Note: Cancel** clears and closes the Cuvette Lot Number Entry dialog box without saving entries. **Exit** closes the Cuvette Lot Number Entry dialog box.*

Entering QC Lots

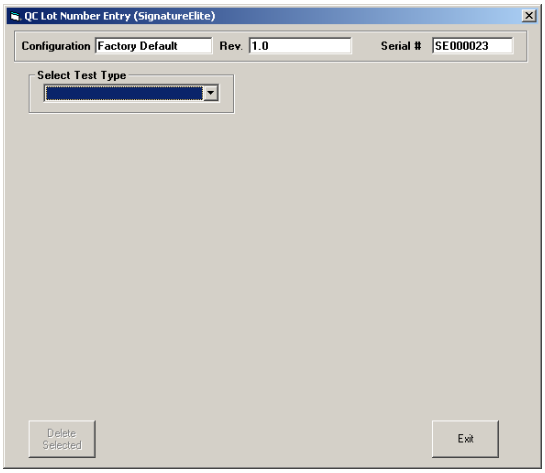
Up to five quality control lot numbers, expiration dates, and expected ranges can be entered per assay type for both level 1 (normal) and level 2 (abnormal) liquid controls. Selection or scanning of a QC lot number is only allowed when **Required**, **Scan only**, and/or **Pre-stored only** is specified for *QC Lot Options* (see page 56).

***Note**: If more than five QC lot numbers per assay are scanned or entered for level 1 and/or level 2 controls, the lot number(s) with the closest expiration date will be deleted.*

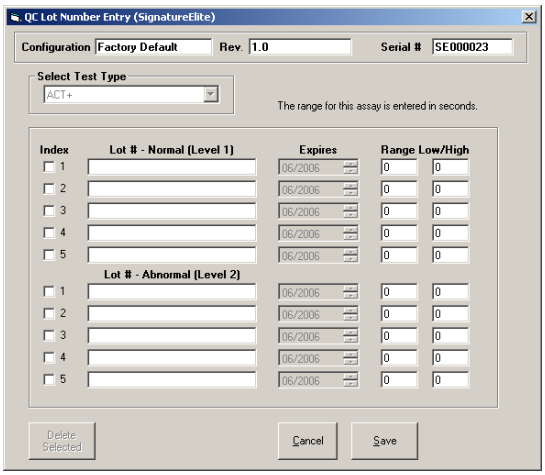
***Note**: QC lot number information may be scanned using the barcode scanner through the Supervisor menu and uploaded to Configuration Manager (page 18). If needed, the expected ranges can then be manually changed by the supervisor in Configuration Manager.*

***Note**: QC lot number information that is manually entered into the HEMOCHRON Signature Elite instrument when running a QC test is only saved to that particular QC test record and is not uploaded to Configuration Manager.*

1. Click **QC Lots** on the Configuration Module dialog box (page 52) to display the QC Lot Number Entry dialog box:



2. Select an assay from the **Select Test Type** drop-down list to display the form for entering QC lot numbers, expiration dates, and expected ranges for that assay:



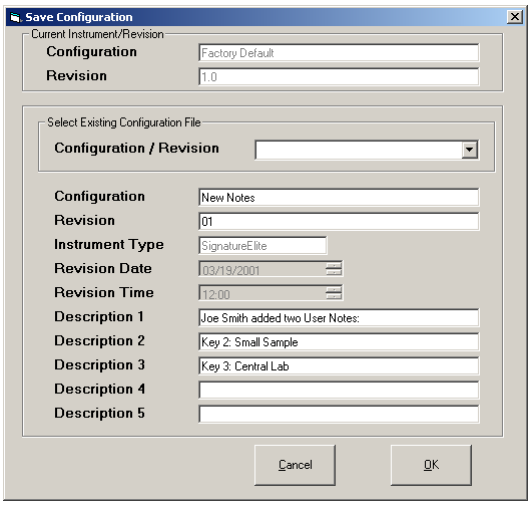
3. Enter the QC lot number, expiration date, and low and high limits for level 1 (normal) and/or level 2 (abnormal) controls. The limits that are entered may be from the expected range contained in the labeling for the controls or from an expected range specified by the supervisor.
4. Click **Save** to save the QC lot number information for the specified assay.

Note: Cancel *clears and closes the QC Lot Number Entry dialog box without saving entries.* ***Exit*** *closes the QC Lot Number Entry dialog box.*

Saving Modified Configuration Data

After configuration data has been modified, the data must be saved before it can be downloaded to an instrument or used in the future.

1. Click the **Save Configuration** button on the Configuration Module dialog box (page 52) to display the Save Configuration dialog box:



2. Enter a file name and/or revision for the configuration data to be saved:
   - To save the configuration data under a new file name, enter a name for the new configuration file in the *Configuration* field and enter the revision number for the file in the *Revision* field.
   - To save the configuration data as a new revision of an existing file name, select the existing file name and revision from the *Configuration/Revision* field and enter the new revision number for the file in the *Revision* field.
   - To overwrite an existing configuration file, select the existing file name and revision from the *Configuration/Revision* field.
3. (Optional) Enter information to describe the new configuration in the *Description 1* through *Description 5* fields.
4. Click **OK** to save the configuration, then click **OK** to respond to the confirmation prompt.

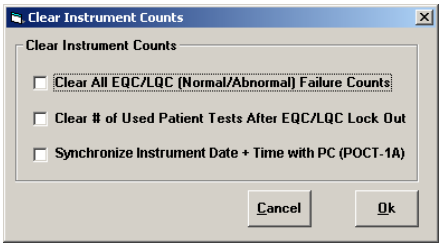
Note*: If an existing configuration file is being overwritten, a confirmation to overwrite the file is displayed. Click* ***Yes*** *to overwrite the file or click* ***No*** *to cancel the operation.*

Writing Configuration Data to an Instrument

After configuration data have been modified and saved, the data from the configuration file (or any other saved configuration file) can be downloaded to a HEMOCHRON *Signature Elite* instrument.

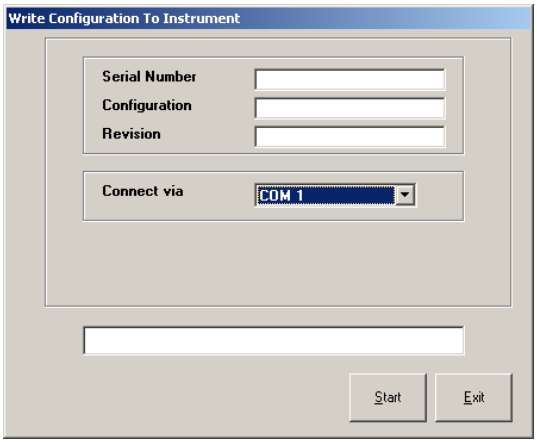
To Write Configuration Data to an Instrument:

1. (If needed) Connect the instrument to the PC (see page 23).
2. (If needed) Start HEMOCHRON *Configuration Manager* and select the configuration file that is to be downloaded (see page 51).
3. Click the **Clone Instrument** button on the Configuration Module dialog box (page 52) to display the Clear Instrument Counts dialog box:


Clear Instrument Counts
Clear Instrument Counts
Clear All EQC/LQC (Normal/Abnormal) Failure Counts
Clear # of Used Patient Tests After EQC/LQC Lock Out
Synchronize Instrument Date + Time with PC (POCT-1A)
Cancel
Ok

Note: *The Clear Instrument Counts dialog box allows the user to specify whether failure counts and 911 use counts will be reset on cloning and to synchronize the instrument time and date with the PC time and date when using the POCT-1A communication protocol.*

4. Click **OK** to continue.
5. The Write Configuration dialog box is displayed:



6. Establish communication to the instrument as described on pages 45 and 46.

   Note*: If the instrument is connected over a network, select* ***<Listen on Network>*** *from the drop-down list in the Connect via box. Otherwise, if prompted, designate the COM port by selecting it from the drop-down list.*

7. Click **Start**. Progress information is displayed in the status line.

   Note*: If the ITC proprietary communication protocol is used,* ***Transferring Data*** *is displayed on the connected HEMOCHRON Signature Elite instrument during data transfer. If the connection is not made, an error message is displayed on the personal computer. Select* ***Retry*** *on the error message box to make the connection.*

   Note*: If the POCT-1A communication protocol is used, specific messages indicate the progress of data transfer. If the connection is not made, the instrument will beep, display* ***Network Timed Out!****, and prompt that the instrument is ready to accept a cuvette.*

8. A message box is displayed when writing of the configuration data is complete. Click **OK** to acknowledge the message.

Printing Instrument Configuration Data

All of the configuration parameters for an individual instrument or a configuration file can be printed.

1. (If needed) Connect the instrument to the PC (see page 47).
2. (If needed) Start HEMOCHRON *Configuration Manager* and select the configuration file that is to be downloaded (see page 51) or click on **Read Configuration From Instrument**.
3. Click the **View/Print Configuration** button on the Configuration Module dialog box (page 52) to display the configuration report.
4. Click the Print icon to print the report.
   Click the Export icon to export the report as a specified file type to a specified drive.
   Click the Refresh icon to update the report.
5. Click the Cancel icon to close the report window.

Closing the Configuration Module

After configuration data has been processed, the configuration module can be closed.

1. Click the **Exit** button on the Configuration Module dialog box (page 52) to cancel display of the configuration module dialog box.

Displaying and Printing Specific Configuration Reports

Several types of configuration reports can be displayed and printed. The reports provide an audit trail for specific information from all configuration files (or for all instruments) stored in the database:

Specific Report	Description
Instrument Options Listing	Lists instrument options.
Operator Table Listing	Lists the name, OID, PIN, and certification expiration date for each operator.
QC Lock-Out Control Listing	Lists selections for EQC/LQC Lockout.
User Notes Listing	Lists user notes that have been defined.
Lot Number Listing (*Signature Elite* v2.0 or higher only)	Lists lot numbers and expiration dates for cuvettes that have been defined for each assay. Lists lot numbers, expiration dates, and expected ranges for controls that have been defined for each assay.
Audit Trail Report	Lists the changes made to configuration data files. The report can be sorted by date or user name.

To Prepare a Specific Configuration Report:

1. Select **Reports** in the Configuration Manager main menu.
2. Select the desired report type from the **Reports** menu. A drop-down menu is displayed for selecting the instrument type (*Signature Elite* or *Signature+*).
3. Select the instrument type. The specified information is displayed.
4. Click the Print icon to print the report.
   Click the Export icon to export the report as a specified file type to a specified drive.
   Click the Refresh icon to update the report.
5. Click the Cancel icon to close the report window.

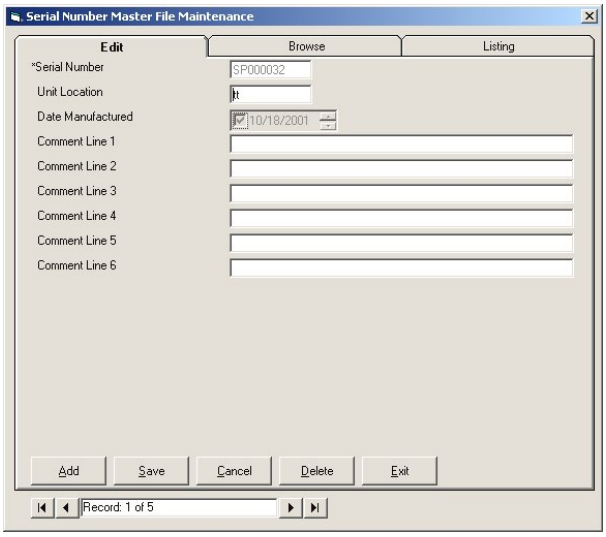
MASTER FILE MAINTENANCE

The Master File Maintenance function of HEMOCHRON *Configuration Manager* allows a record for a HEMOCHRON *Signature Elite* instrument or IP address to be added, modified, or deleted.

Manually Adding an Instrument

The supervisor can add a new instrument to the table of instrument serial numbers and unit locations.

1. Select **Serial Number Master File** from the **Master File Maintenance** menu. The Serial Number Master File Maintenance dialog box is displayed:



2. Click **Add** to display a blank information form.
3. Enter the serial number, unit location, and comment, if desired. The Date Manufactured is read from the instrument.

   Note: *Entries are not case-sensitive.*
4. Click **Save**. The new instrument record is saved.

Automatically Adding an Instrument

The Serial Number Master File is automatically updated whenever configuration data is read from an instrument that is not currently included in the Serial Number Master File. A message box is displayed to confirm the update:

Instrument SE000024 has been added to the database.
To view the database, use menu option "Master File Maint." -> "Serial Number Master File".
OK

Click **OK** to acknowledge the update.

Updating an Instrument Record

The supervisor can modify or delete a record for an existing instrument.

1. Select **Serial Number** from the **Master File Maintenance** menu. The Serial Number Master File Maintenance dialog box is displayed listing information for the first instrument record in the database.

   Note: *The record number and total number of records in the database are displayed at the bottom of the dialog box.*

2. Use the scroll buttons at the bottom of the dialog box to display the record to be updated.
3. Update the information as needed. Click **Delete** to delete the instrument record.

   Note*: Entries are not case-sensitive. The Serial Number field and Date Manufactured field cannot be changed. To change the serial number, delete the record and add a new record for the new serial number.*

4. Click **Save**. The updates are saved.

   Note: *Click **Exit** to return to the main window.*

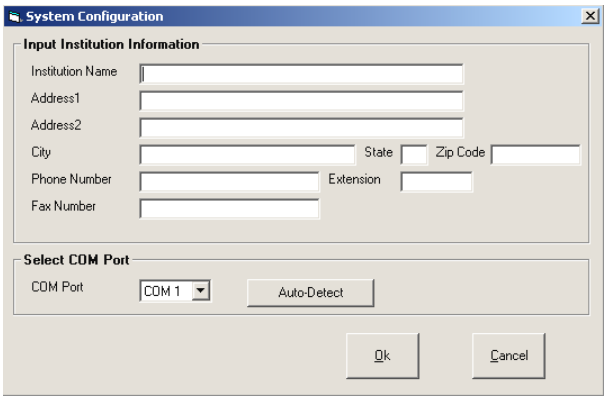
CONFIGURATION MANAGER UTILITIES

The HEMOCHRON *Configuration Manager* Utilities allow supervisors to maintain the HCM database:

Function	Description
System Configuration	Update institution name, address, and contact information. Enter the PC COM port used, or automatically detect it.
Security	Update or delete HCM user records, including user name file, password, or security level.
Set Instrument Date and Time	Synchronize date and time between an instrument and the PC.
Purge Configuration Data	Remove a configuration file from the database.
Rebuild Database	Compress and repair the specified tables. (**Compress** reduces the size of database files. **Repair** re-indexes each table).
Convert HCM Data from Ver 1.0 or **Ver 2.0**	Converts data from HEMOCHRON *Configuration Manager* V1.0 or V2.0 to V3.0.

Updating Laboratory Information and/or PC COM Port

1. Select **System Configuration** from the **Utilities** menu. The System Configuration dialog box is displayed:



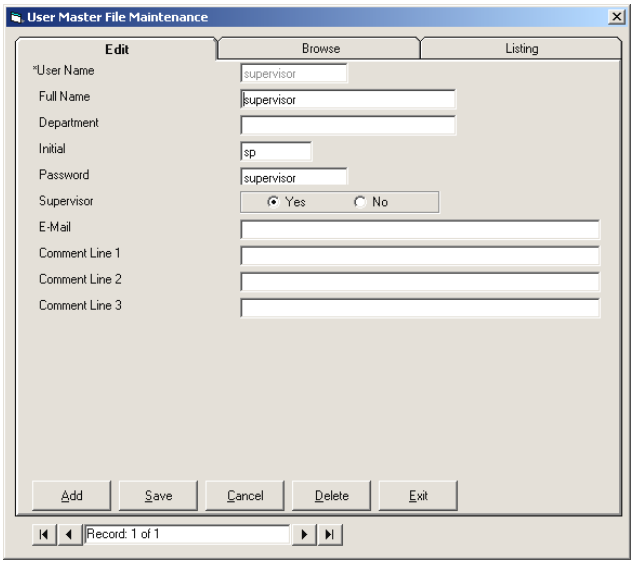
Note: *Refer to page 48 for instructions on entering information and selecting a COM port.*

Adding a User

The supervisor can add a new user to the table of operators of HEMOCHRON *Configuration Manager*. The new user will be assigned a password and access level.

***Note**: Any user can perform all operations until at least one user with an access level of Supervisor is defined. Once a supervisor is defined, only the supervisor can create and edit any files in Configuration Manager. All other users will only be allowed to view and print.*

1. Select **Security** from the **Utilities** menu. The User Master File Maintenance dialog box is displayed:



2. Click **Add** to display a blank user information form.
3. Enter the user name, password, e-mail address and other information.

   ***Note:** Entries are not case-sensitive.*
4. Select **Yes** in the Supervisor field if the user is to have supervisor-level access.
5. Click **Save**. The new user record is saved.

Updating a User Record

The supervisor can modify or delete a record for an existing user.

1. Select **Security** from the **Utilities** menu. The User Master File Maintenance dialog box is displayed listing information for the first user record in the database.

   ***Note:** The record number and total number of records in the database are displayed at the bottom of the dialog box.*
2. Use the scroll buttons at the bottom of the dialog box to display the record to be updated.
3. Update the name, password or access level as needed. Click **Delete** to delete the user record.

   ***Note**: Entries are not case-sensitive. The User Name field cannot be changed. To change User Name, delete the record and add a new record for the new User name.*
4. Click **Save**. The updates are saved.

   ***Note:** Click **Exit** to return to the main window.*

   ***Important:** The user name "Supervisor" cannot be deleted from the database; however the password can be changed.*

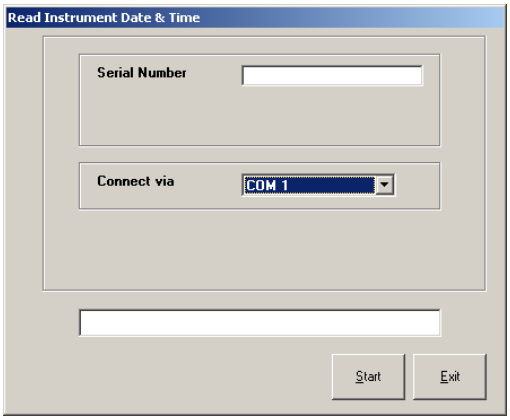
Setting the Instrument Date and Time

The time clock of the HEMOCHRON *Signature Elite* instrument must be synchronized with that of the HEMOCHRON *Configuration Manager* PC so that correct starting times are used for system lockouts.

***Note**: The time and date format that are used on an instrument may not be the same as that used in HEMOCHRON Configuration Manager.*

Setting the Instrument Date and Time when the ITC Communication Protocol is Used:

1. Start HEMOCHRON *Configuration Manager* (see page 48).
2. Select **Set Instrument Date and Time** from the **Utilities** menu. The Read Instrument Date and Time dialog box is displayed:



3. Designate the COM port by selecting it from the drop-down list.

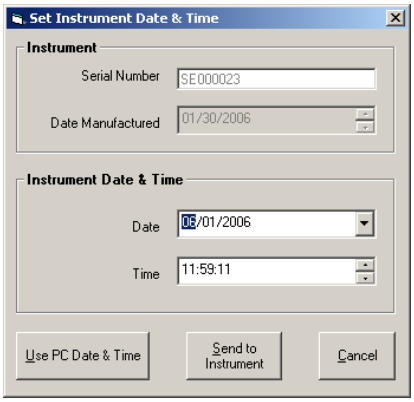
   ***Note**: The instrument must be connected to a COM port. If the instrument is connected to a network, the date and time must be set at the instrument as described on page 18.*

4. Click **Start**. Progress information is displayed in the status line.

   ***Note**: **Transferring Data** is displayed on the connected HEMOCHRON Signature Elite instrument during data transfer.*

   ***Note**: If the connection is not made, an error message is displayed on the personal computer. Select **Retry** on the error message box to make the connection.*

5. At the completion of data transfer, the Set Instrument Date and Time dialog box is displayed:



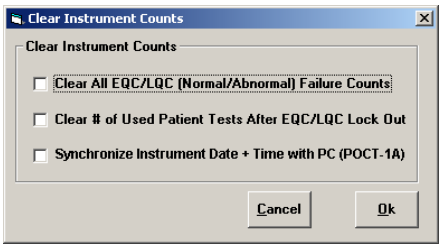
***Note:** The Instrument information is read-only and cannot be changed by the user.*

6. Set the date and time using the up and down arrow keys. Or, click **Use PC Date and Time** to display the PC date and time.
7. Click **Send to Instrument** to synchronize the connected instrument with the displayed date and time.

Setting the Instrument Date and Time when the POCT-1A Communication Protocol is Used:

1. Start HEMOCHRON *Configuration Manager* (see page 48).
2. Read the configuration from the instrument that is connected over the network (see page 51).

   Note: *When the POCT-1A communication protocol is used, HEMOCHRON Configuration Manager cannot communicate with the instrument over the COM port.*
3. Click the **Clone Instrument** button on the Configuration Module dialog box (page 52) to display the Clear Instrument Counts dialog box:

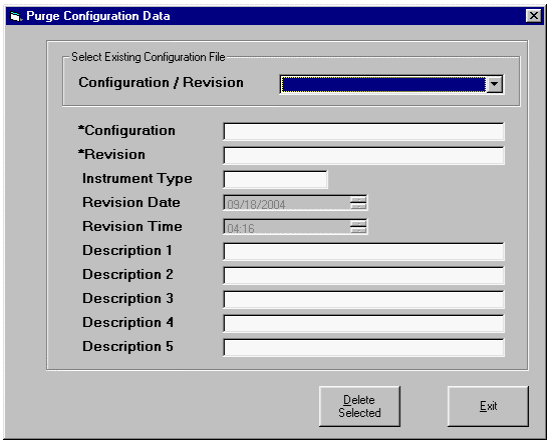

Clear Instrument Counts
Clear Instrument Counts
Clear All EQC/LQC (Normal/Abnormal) Failure Counts
Clear # of Used Patient Tests After EQC/LQC Lock Out
Synchronize Instrument Date + Time with PC (POCT-1A)
Cancel
Ok

4. Select **Synchronize Instrument Date + Time with PC (POCT-1A)**. Do not select the other two options.
5. Select **OK**. The Write Configuration dialog box is displayed (page 66).
6. Click **Start**. Progress information is displayed in the status line.
7. A message box is displayed when writing of the configuration data is complete. Click **OK** to acknowledge the message.

Purging Configuration Data

An existing configuration file can be removed from the *Configuration Manager* database. A record of the file removal is maintained in the audit trail.

1. Select **Purge Configuration Data** from the **Utilities** menu. The Purge Configuration Data dialog box is displayed:



2. Use the drop-down arrow to select the configuration file that is to be purged. The information for the configuration file is displayed.

   Note: *The information is read-only and cannot be changed by the user.*

3. Click **OK**. The selected configuration file is purged from the database.

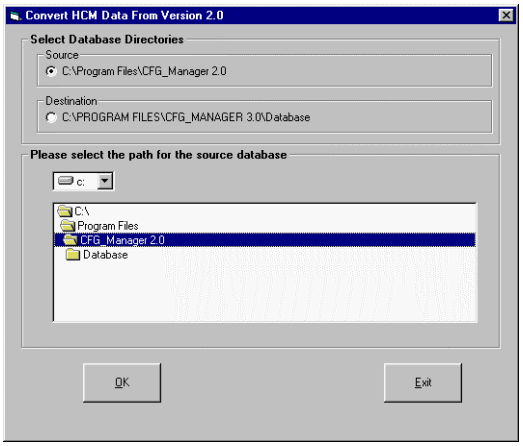
Rebuilding the Database

1. Select **Rebuild Database** from the **Utilities** menu. The Rebuild Database dialog box is displayed:

2. Select the operation (**Compress Database**, or **Repair and Compress Database**) that is to be performed.
3. Click **OK**. The databases are repaired and/or compressed.

Converting the Database

1. Select **Convert HCM Data from Ver 1.0 (**or **2.0)** from the **Utilities** menu. The Convert HCM Data from Version 1.0 (or 2.0) dialog box is displayed:



   Note: *The source and destination paths are shown. These cannot be modified.*

2. Click **OK** to start the conversion. A progress bar is displayed during the conversion, and a message box confirms the data is successfully converted.

Configuration Manager Error Messages

Problem	Cause	Corrective Action
CHKSUM error during data transfer	Other software applications are open during data transfer.	Close all applications including anti-virus programs during communications.
Communication error/ Initialization error	Incorrect cable is used or cable is not completely connected.	Ensure proper cable is being used. Check cable connections.
No COM Port	No COM Port available.	Use HCM to detect available COM Port
Text crowded / Overlapping on screen	Older computer graphics card	Does not affect program. Printouts will be correct.

Instrument Error Messages

The error messages that may be displayed while operating the HEMOCHRON *Signature Elite* instrument are listed below. The probable cause and corrective action are shown for each message.

Some messages designate a test or sample fault. This message is included in the printed results for the affected sample. A list of these messages can be found in *Acronyms for Error Messages* on page 44.

If needed, contact ITC Technical Support by phone at +1-732-548-5700, by FAX at +1-732-548-9824, or by e-mail at techsupport@itcmed.com.

Error Message	Cause	Corrective Action
RTC....FAULT	Can not communicate with external Real Time Clock.	Contact ITC Technical Support.
CHARGE BATTERY	Battery power depleted below predetermined level.	Connect to AC/DC Power Module and charge battery for 8 hours.
BATTERY FAULT	Battery is discharged.	Charge battery for 8 hours. If message persists, contact ITC Technical Support.
EXTERNAL TOO HIGH	AC/DC Power Module voltage exceeds 12.7 volts.	Disconnect the AC/DC Power Module. Contact ITC Technical Support.
BATTERY TOO HIGH	Battery voltage exceeds 8.8 volts.	Disconnect the AC/DC Power Module. Contact ITC Technical Support.
Heater Too Cool	Incubator remained below 36 °C after 90 seconds of warming on external power or for up to 150 seconds on battery.	Repeat test, then charge battery. If message persists, contact ITC Technical Support.
Heater Too Hot	Incubator exceeded 38 °C for 2.5 seconds.	Repeat test with new cuvette. If message persists, contact ITC Technical Support.

Error Message	Cause	Corrective Action
Detector Fault	Light path between LED and detectors is blocked.	Repeat test with new cuvette. If message persists, contact ITC Technical Support.
Detector Blocked	EQC is being run while a cuvette is inserted.	Remove the cuvette and repeat the EQC.
Sample Pos Fault	Sample has moved outside of testing area in cuvette.	Contact ITC Technical Support.
ASSAY LOCKED CALL SUPERVISOR	The QC failure limit has been exceeded.	Remove the cuvette. Contact the supervisor.
MACHINE LOCKED CALL SUPERVISOR	The EQC failure limit has been exceeded.	Contact the Supervisor.
Sample Not Seen	Sample has not reached front detector in specified time period.	Repeat test with new cuvette. If message persists, contact ITC Technical Support.
Cuvette Removed	Cuvette was prematurely removed from instrument while testing in progress.	Repeat test with new cuvette.
Sample Too Large/ Sample Too Small	Excess or insufficient sample.	Repeat test with new cuvette.
Premature Sample	Sample was detected at front detector before specified time period. May occur if sample is added before pump-priming sequence is complete.	Repeat test with new cuvette. If message persists, contact ITC Technical Support.
MEMORY FAULT	Malfunction in the computer's memory.	Contact ITC Technical Support.
START Timed Out	START key was not pressed within 5 minutes after entering ready mode.	Remove cuvette and repeat test with new cuvette.
Unsupported Assay	Cuvette cannot be identified by instrument.	Remove cuvette and repeat test with new cuvette. Use ITC cuvettes only.
No Data Stored	Operator attempted to print data when none is stored in database.	N/A
User Abort	The test was aborted by the user.	Repeat test.
Invalid Lot #	The barcoded cuvette or QC lot number label that was scanned was not recognized.	Check the label for damage, then repeat the scan.
	The incorrect format was entered for the lot number.	Repeat the entry using the correct format.
	The lot that was scanned does not match the cuvette test type.	Verify the test type, then rescan the lot.

Error Message	Cause	Corrective Action
Lot Expired	The cuvette and/or QC material that is being used has reached its expiration date.	Remove the cuvette and repeat the test using supplies that are within their expiration date.
Action Denied	Date/Time cannot be changed if QC Lockout is required, or Date/Time function is denied through Configuration Manager.	Supervisor needs to reconfigure instrument using HCM.
Disallowed Assay	Assay performance has been prohibited via *Configuration Manager*.	Supervisor needs to reconfigure instrument using HCM.
	The table of cuvette or QC lots is empty or contains only expired lots.	Supervisor needs to reconfigure instrument using HCM.
	The QC interval is set to zero in *Configuration Manager*.	Supervisor needs to reconfigure instrument using HCM.
Cannot erase DB	Erasing patient and/or QC database is not allowed.	Supervisor needs to reconfigure instrument using HCM.
INR< 0.8 INR > 10.0 APTT < 20	Test result is outside clinical range.	Repeat test with new cuvette.
Out of Range-Lo	Test result is outside clinical range. Sample has clotted prematurely, or did not mix correctly in cuvette. Bubbles may be present.	Repeat test with new cuvette.
Out of Range-Hi	Test result is outside clinical range.	Repeat test with new cuvette.
Check Time/Date	Low Battery or RTC has lost its Time/Date Tracking.	Enter or verify Time & Date. Charge Battery.
Dark Photo Fault	Hardware malfunction.	Contact ITC Technical Support.

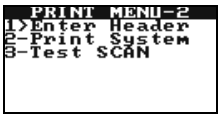
Verification of Barcode Scanner

Check the barcode scanner by scanning a test barcode.

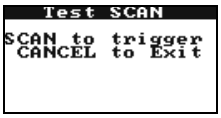
To Test the Barcode Scanner:

1. Press **PRINT/SCAN** to display the Print menu:

2. Press **7** to display the second page of the Print menu:



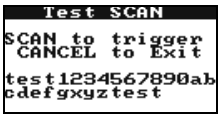
3. Press **3** to test the scanner:



4. Position the scanner port (see page 5) approximately four inches from the barcode label that is shown below:

Note: *The barcode shown above is formatted as Code 128.*

5. Press **PRINT/SCAN**. The characters that are read from the barcode are displayed in the screen:



6. Verify that **test1234567890abcdefgxyztest** is displayed.
7. Press **CANCEL** three times.

SERVICE AND MAINTENANCE

Routine Maintenance

Inspect and clean the cuvette opening as required. Remove residual dried blood or other foreign matter using water-moistened cotton swabs.

Remove any residual water with dry cotton swabs. If a disinfectant is needed, use a 0.5% solution of sodium hypochlorite or a 10% dilution of household bleach in water. Wipe instrument with a water-dampened cloth to remove residual bleach from the plastic surfaces.

Apply solution to clean and disinfect areas contaminated with blood. DO NOT use solvents or strong cleaning solutions as they may damage the instrument's plastic components. Routine maintenance other than cleaning normally is not required.

Service

The HEMOCHRON *Signature Elite* instrument is almost completely self-monitoring and has no user serviceable parts.

It monitors internal circuitry and reports problems to the display screen automatically. Malfunctions are indicated by error messages detailed in the section "Troubleshooting."

Battery Care

To optimize battery life, it is recommended that the HEMOCHRON *Signature Elite* instrument be run on its battery during the day. It can be plugged into a Hospital Grade AC outlet overnight to allow the batteries to recharge. The life of the lithium battery is optimized when the battery is exercised in this manner.

A fully charged battery will operate as defined in the *Operation* specifications section on page 12.

When the batteries are drained to the point that valid testing cannot be performed, the instrument will display "CHARGE BATTERY" (see "Troubleshooting"). At this point, the instrument must be plugged in for operation and recharging. Once plugged into a Hospital Grade AC outlet, the instrument can be used immediately.

Instrument Disposal

If disposal is necessary, follow local regulations for disposal of electronic devices.

SAFETY STANDARDS

The HEMOCHRON *Signature Elite* instrument complies with the following safety standard requirements and directives:

CSA C22.2. 601.1.	Medical Electrical Equipment – General Requirements for Safety
EN 60601-1 / IEC 60601-1/ UL 60601-1	Medical Electrical Equipment – General Requirements for Safety
EN 60601-1-2 / IEC 60601-1-2	Medical Electrical Equipment – Part 1-2 – General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
EN 60825-1	Safety of Laser Products – Part 1: Equipment Requirements, Classification, and User's Guide
EN 61000-3-2	Electromagnetic Compatibility – Limits – Limits for Harmonic Current Emissions
EN 61000-3-3	Electromagnetic Compatibility – Limits – Limitation of Voltage Changes, Voltage Fluctuations and Flicker in Public Low-voltage Supply Systems
EN 55011	Industrial, Scientific and Medical (ISM) Radio Frequency Equipment – Radio Disturbance Characteristics – Limits and Methods of Measurement
EN 61326	Electrical Equipment for Measurement, Control and Laboratory Use – EMC Requirements
Directives: 89/336/EEC and as amended by 91/263/EEC, 92/31/EEC, 93/68/EEC, 98/13/EC, and 98/79/EC.	

Equipment Classifications As Defined Per UL 60601-1:2003/ IEC60601-1 2nd Edition

Protection Against Electrical Shock: Class I, Internally Powered Equipment with no applied parts

Protection Against Ingress of Liquids: Ordinary (no protection as defined by IEC 529)

Product Cleaning and Disinfection: Only according to recommendations of the manufacturer's accompanying documentation

Mode of Operation Of Equipment: Continuous

Degree of Safety of Application in the Presence of Flammable Anesthetic Mixture With Air, Oxygen or Nitrous Oxide: Not Suitable

NOTE: as defined in the above standards, the classification of Not Suitable is not intended to indicate that the instrument is not suitable for use in an Operating Room (OR) environment. Rather, it is intended to indicate that the instrument is not suitable for use in the direct presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide.

All relevant documentation is kept on file at ITC in Edison, NJ.

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